# AN INQUIRY INTO DIFFERENCES IN PATIENT OUTCOMES BY OBSERVING DIETITIAN AND NURSE PRACTITIONER MANAGEMENT OF HYPERLIPIDEMIA

A Graduate Research Project

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In Partial Fulfillment of the

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of

Master of Health Administration

by

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This study was performed to cross check the differences between a dietitian and a nurse practitioner when dealing with patients to lower there overall cholesterol level. The study was performed at Irwin Army Community Hospital, Fort Riley, KS..

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## DEDICATION

As our journey through life unfolds, we are occasionally permitted to stop and reflect on where we have been and where we are going. The completion of this graduate research project is one such event. It is the culmination of two years of hard work, wonderful learning experiences, and the memory of the many, many people who have helped me along the way.

The phrase "no man is an island, no man stands alone," holds special meaning for me, for while it is my name which appears on this work, it is because of the hundreds of people that have held me with their suggestions, criticism, and interest that I now conclude this project. To these many friends I dedicate this work.

In particular, I would like to mention the superlative support from the staff at Irwin Army Community Hospital, Fort Riley, Kansas. I could not have asked to work with a finer group of dedicated professionals. I will always remember them.

I also dedicate this work to my family; my mother and father and my own dear family. Two of our five children have been born while I have been a Baylor student. While it was difficult, at times, to meet the needs of the children and the course, their addition to the family has truly been a blessing.

Finally, I dedicate this work to my lovely wife, Diana. Her loving support through the years has been my strength through difficult times. She has been, is, and will always be, my truest and best friend.

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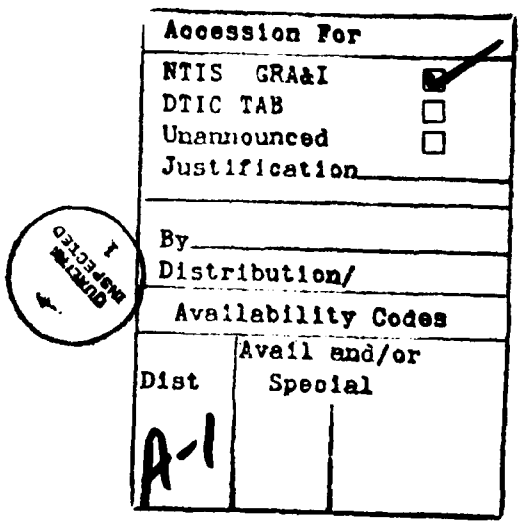


# INTRODUCTION

## ORIENTATION

Dietitians have traditionally seen themselves as uniquely qualified to deal with medical problems involving nutrition. Indeed, their specific training in nutrition intervention has generally been considered to be superior to any other health care provider including physicians (Douglas, 1986; Wilber 1982). Some physicians have conceded this point in the treatment of certain disease states and have urged their colleagues to refer patients to dietitians for nutrition counseling (Hoeg, Gregg, and Brewer, 1986).

But in today's environment of increasing competition in health care (Goldsmith, 1984), dietitians are encountering competent, well-trained nutrition counselors outside their own profession. Physicians are including more nutrition education in their training programs such as in family practice residencies (Rubenstein and Berkoff, 1984; Creager, Turner, and Cook, 1984). Nurses are incorporating more diet information in their patient teaching. Nurse practitioners in particular are becoming more aggressive in pursuing the nutrition counseling market (for examples, see Blair, 1986; Popkess-Vawter, 1982).

A review of the literature reveals nothing concerning the merits of nutrition education provided by dietitians as compared to that delivered by nurse practitioners. Thus, the question arises: is there a measurable difference in patient outcome based on management of an uncomplicated disease

state provided by a dietitian and a nurse practitioner? The answer may have an impact in clinical and management decisions regarding staffing of health care providers.

For example, if patients referred to a nurse practitioner for counseling show more improvement such as in weight loss, reduced cholesterol, or maintenance of normal blood glucose levels than those seen by a dietitian, an administrator could possibly elect to staff a position held by a dietitian with a nurse practitioner. It is recognized, of course, that present Joint Commission on Accreditation of Hospitals (JCAH) standards call for "qualified dietitians to supervise the nutritional aspects of patient care and assure that quality nutritional care is provided to patients." (Joint Commission on Accreditation of Hospitals, 1985, p. 12.) But in other portions of the Dietetic Services section of the JCAH manual it states "qualified" or "authorized designees" in addition to dietitians may perform the services outlined by the Joint Commission (JCAH, 1985, pgs. 11-22). "Qualified designees" may include nurse practitioners, especially in areas where nurses are traditionally employed, such as in outpatient clinics, on patient wards in hospitals, and in physicians' offices. Patients seen in these settings may be suffering from medical conditions in which diet plays a primary or secondary role such as in hypertension, diabetes mellitus, and coronary heart disease. Dietary counseling by nurse practitioners can easily be included in a care plan. It may be part of a treatment plan in which the nurse practitioner may use a variety of care techniques including behavior modification, physical

education, and prescription of medication (Pepper, 1986; Poole, 1986; AR 40-48, 1984; McCauley and Weaver, 1983).

Dietitians are not authorized to prescribe medication for these types of diseases but their preparation of physiology, biochemistry, counseling and education provide them with skills especially well suited to their dietary treatment (Douglas, 1986). However, if nurse practitioners are equally well prepared in these areas as well as in pharmacology and diagnosing, administrators may decide that greater versatility in patient care is achieved by hiring nurse practitioners instead of dietitians. The Menninger Foundation in Topeka, Kansas, for example, employs nurses and social workers in its eating disorder unit but no dietitians (Page, Personal Communication, January 21, 1987). In order to determine if patients with the same medical condition have different outcomes when seen by a nurse practitioner or dietitian, this research project was undertaken.

## PROBLEM STATEMENT

The purpose of this project is to determine whether total cholesterol of moderately elevated levels in out-patient volunteers is reduced by clinical counseling provided by a dietitian or by counseling from a nurse practitioner.

## OBJECTIVES

This study sought to determine whether one group of volunteers had a statistically significant reduction in total cholesterol after receiving counseling from a dietitian or nurse practitioner. This was determined by meeting the following objectives:

a. Identifying a convenient sample of patients eligible for care at Irwin Army Community Hospital, Fort Riley, Kansas, who were at moderate risk for the development of coronary heart disease due to mildly elevated total cholesterol.

b. Dividing this group into two groups. One group received counseling from the dietitian. The other received counseling from the nurse practitioner.

c. The two health care providers gave instructions and follow-up as appropriate without the intervention of the researcher or other health care providers in the hospital.

d. Recalling volunteers after an appropriate time to the hospital in order to test the cholesterol level. Body weight at the beginning and end of the study and the number of visits with the practitioner were noted. Comparison evaluation of health care provider instruction regarding smoking, exercise, weight and diet was conducted.

## CRITERIA

Volunteers for the study were eligible for medical care within Department of Defense guidelines. This would include active duty military, retired military and their dependents. Subjects under the age of 20 were excluded.

Volunteers were selected at random by reviewing Sequential Multiple Analyser (SMA)-12 laboratory reports.

Reports showing total cholesterol between the 75th and 94th percentile were selected.

Reports of fasting glucose levels above 128 mg/dg were excluded.

Only reports which indicate the patient was in a fasting state were used.

Data collection consisted of age, sex, body weight at the beginning and end of the study, cholesterol levels at the beginning and end of the study, and the number of visits by the volunteer to the health care provider during the study period. Smoking cessation and exercise counseling were compared.

Data was analyzed to determine whether statistical differences between the two study groups existed.

## ASSUMPTIONS

For the purpose of this research, it was assumed that:

a. The dietitian and nurse practitioner were already providing treatment to patients with mildly elevated cholesterol levels in accordance with the limits outlined in Army Regulation 40-48 (1984).

b. The dietitian and nurse practitioner had established procedures and protocols referent to cholesterol management.

c. Cholesterol treatment protocols would be followed by the provider and not be adjusted or changed because of the study.

d. Care plans would be tailored to patient needs and follow-up appointments would be scheduled as deemed appropriate.

e. Some patients may smoke, be overweight, or have hypertension and that the health care providers would address these complaints in concert with cholesterol reduction therapy.

## LIMITATIONS

Hoeg and co-workers (1986) suggest that hyperlipidemic patients be reevaluated every three to six months after cholesterol reduction therapy begins. This study covered a four month period of time for each patient volunteer. The four month interval between the initial contact with the health care provider and the final cholesterol evaluation was considered to be a realistic assessment of the effect of that treatment for cholesterol reduction.

Elevated cholesterol is one of the major risk factors of coronary heart disease (CHD). Other risk factors include hypertension, smoking, diabetes mellitus, and obesity (Gotto et al, 1984). It was recognized that volunteers may exhibit one or more of these risk factors (with the exception of diabetes mellitus, which was excluded from the study). Volunteers were not cohorted for other risk factors. Nevertheless, health care providers were not restricted from addressing these issues in their cholesterol counseling if they were detected during the medical history or review of the patient volunteer's record.

In the treatment of hyperlipidemia, it is often useful to identify phenotypes (Schaefer and Levy, 1985). However, this type of test is more costly than the SMA-12 and, therefore, is not routinely requested by physicians at Irwin Army Hospital. In order to avoid additional costs in time and money, SMA-12 total cholesterol values were used throughout the study.

# LITERATURE REVIEW

Cholesterol is a health concern of national proportions. It is estimated that roughly 20-60 percent of the American adult population have total cholesterol levels which place them at risk for developing CHD (Gotto et al, 1984; Gundy, 1986; US Department of Health and Human Services, 1986). Yet more than half of the adult population is unaware of their own personal cholesterol level, and the risk they may be in (Lenfant, Rifkind, Shucker and Cleeman, 1986).

The risks posed and the resources required to care for patients suffering from cholesterol related diseases such as atherosclerosis and coronary heart disease must be a concern of health administrators as well as the medical community. It is estimated that CHD costs the United States over $60 billion each year in direct and indirect costs. Many of those individuals suffering from these diseases are young, highly productive, and not fully aware of their potential health problems (HHS, 1986).

Health care administrators should become more familiar with the growing body of research in preventive measures for reducing cholesterol. The long term health benefits could significantly reduce demands for health care as the population ages.

Cholesterol - Background:

Though maligned as an undesirable constituent of body chemistry, cholesterol plays many important functions essential to proper health.

"Cholesterol is the precursor of steroid hormones and bile acids, and is an essential constituent of cell membranes (Gagong, 1985, p 249)." It is found only in animal tissues (including seafood, poultry, beef, pork, etc.) though plants also have sterols related to cholesterol. These are not absorbed by the body during digestion; therefore, animal products comprise the only dietary sources of cholesterol.

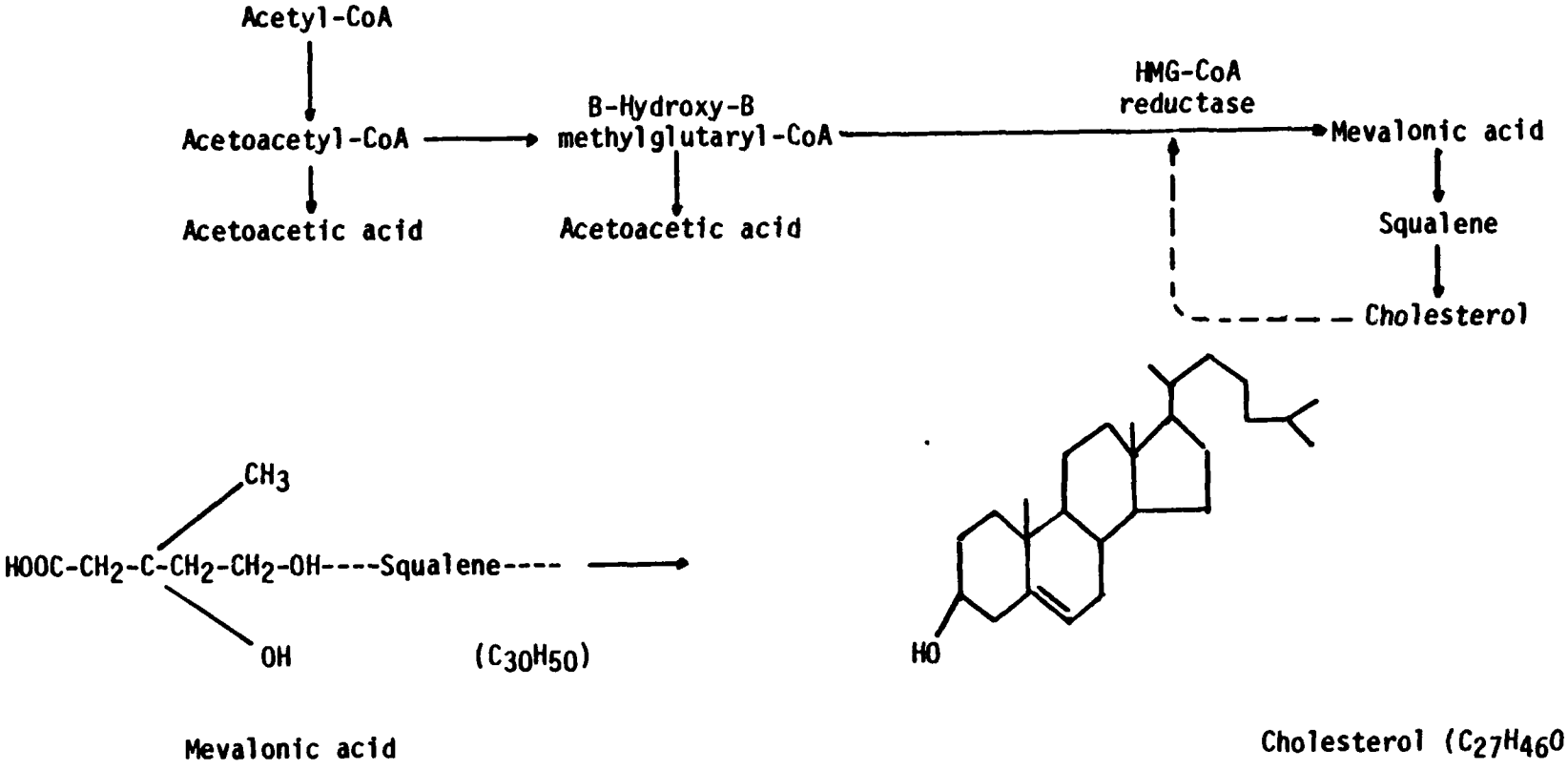
A second, non-dietary source of cholesterol is the body itself. Acetate can be synthesized in the liver into cholesterol. As the cholesterol level in the plasma raises, it acts as its own feedback mechanism to inhibit further synthesis. Thus, when dietary cholesterol is high, internal cholesterol synthesis is reduced (see Figure 1). However, a low dietary cholesterol intake usually leads to a decreased synthesis of cholesterol in the body (Gagong, 1985). In fact, "a one percent reduction of the cholesterol concentration in high risk individuals appears to decrease the risk of cardiac events over a seven to nine year period by approximately two percent (National Institutes of Health, 1985, cited by Hoeg, et al, 1986, p. 514)".

Cholesterol is a fatty compound and as such is classified as a lipid. All dietary lipids must be absorbed from the intestinal tract which is accomplished by a process known as emulsification which involves bile acids (Wood, 1978).

Once absorbed by intestinal mucosa cells, lipids are transformed into lipoprotein compounds to be used by the body. Table 1 provides a list of the lipoproteins found in the plasma, their origin, and their general

FIGURE 1

BIOSYNTHESIS OF CHOLESTEROL




Mevalonic acid

Cholesterol ($C_{27}H_{46}O$)

Note: From Review of Medical Physiology by W. F. Gagong (1985) 12th Edition. Los Altos, California, Lange Medical Publications, p. 250.

TABLE 1

THE PRINCIPAL LIPOPROTEINS.

| | SIZE (nm) | COMPOSITION (%) | | | | ORIGIN |
|---|---|---|---|---|---|---|
| | | PROTEIN | CHOLESTEROL | TRIGLYCERIDE | PHOSPHOLIPID | |
| CHYLOMICRONS | 75-100 | 2 | 5 | 90 | 3 | Intestine |
| CHYLOMICRON REMNANTS | 30-80 | . . . | . . . | . . . | . . . | Capillaries |
| VERY LOW DENSITY LIPOPROTEINS (VLDL) | 30-80 | 10 | 12 | 60 | 18 | Liver and Intestine |
| INTERMEDIATE-DENSITY LIPOPRO-PROTEINS (IDL) | 25-40 | 10 | 30 | 40 | 20 | VLDL |
| LOW-DENSITY LIPOPROTEINS (LDL) | 20 | 25 | 50 | 10 | 15 | VLDL |
| HIGH-DENSITY LIPOPROTEINS (HDL) | 7.5-10 | 50 | 20 | 5 | 25 | Liver and Intestine |

Note: From Review of Medical Physiology by W. F. Gagong (1985) 12th Edition, Los Altos, California, Lange Medical Publications, p. 247.

composition. As show in the table, lipoproteins are composed of proteins called apoproteins and a hydrophobic lipid core of triglycerides and cholesteryl esters (Gagong, 1985). The density of lipoproteins is determined by their content of protein and lipid; the lower the protein content, the lower the density (Schaefer and Levy, 1985). It is common to refer to the various lipoproteins in this manner by referring to them as low density lipoproteins, high density lipoproteins, and so forth.

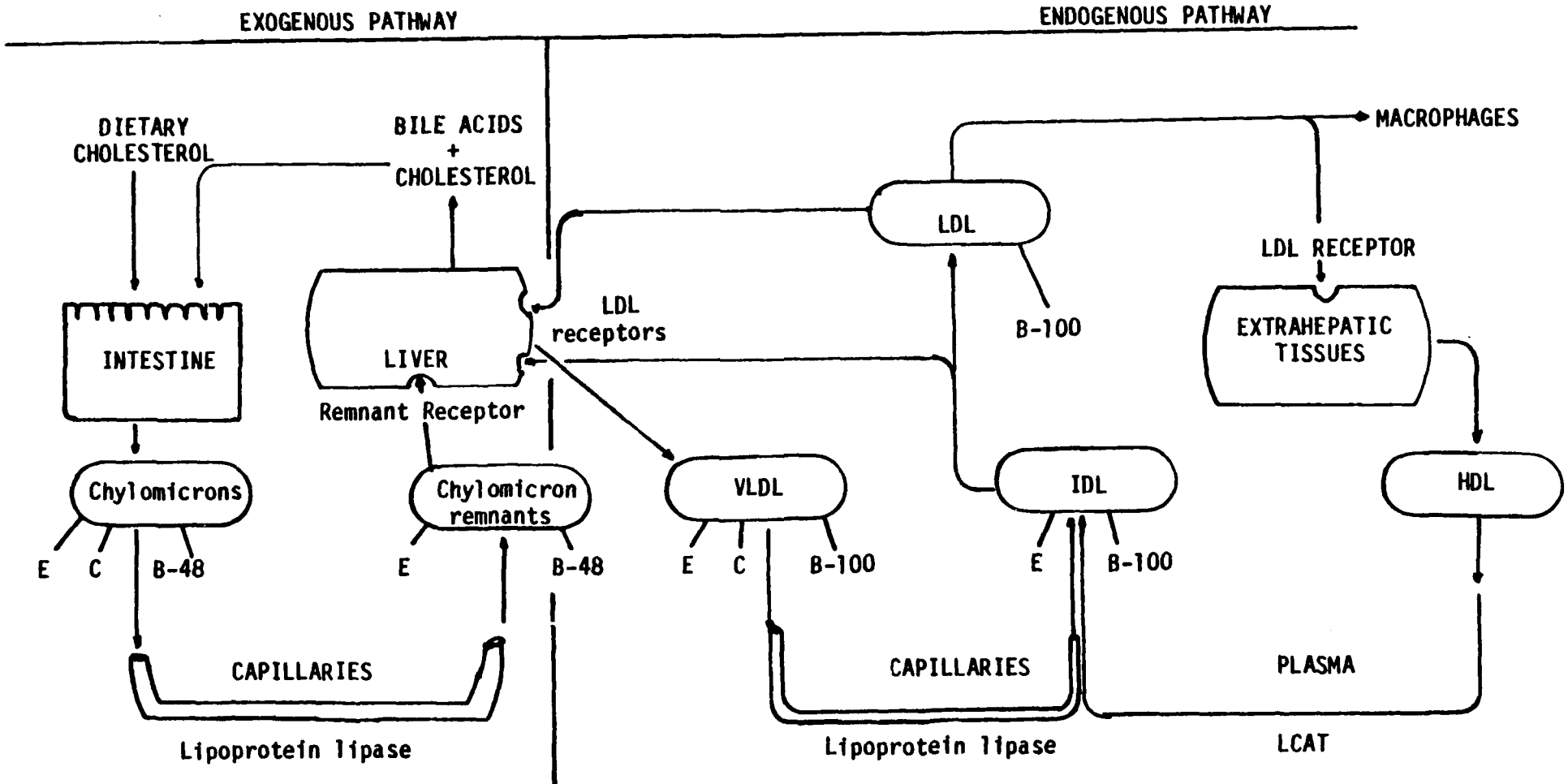
Low density lipoproteins (LDLs) are the major cholesterol bearing lipoprotein in humans although all lipoproteins carry varying percentages of cholesterol. LDLs are formed from chylomicrons and very low density lipoproteins.

Figure 2 depicts the pathways cholesterol follows after digestion. It is initially incorporated into chylomicrons by the intestinal mucosa cells and quickly passes into the peripheral circulation. In the capillaries, chylomicrons are cleared by the enzyme action of lipoprotein lipase found on the surface of capillary cells. Triglycerides, a lipid compound derived from dietary fats or carbohydrates, separate from chylomicrons to be reesterified in fat cells; the chylomicron remnants proceed on to the liver where they are transformed into very low density lipoproteins (VLDLs) (Gotto et al, 1984).

VLDLs leave the liver and are transported in the blood to extrahepatic tissues. As with chylomicrons, VLDLs are cleared from circulation through the action of the enzyme lipoprotein lipase on the cells. Triglycerides are taken up by the cells, the VLDL remnants become intermediate-density lipoproteins

FIGURE 2

LIPOPROTEIN SYSTEMS FOR TRANSPORTING LIPIDS




Note: From Review of Medical Physiology by W. F. Gagong (1985) 12th Edition, Los Altos, California, Lange Medical Publications, p. 248.

(IDLs) and are taken back to the liver. Here they are converted to low-density lipoproteins (LDLs) (Gagong, 1985).

LDLs provide cholesterol to the body, satisfying the cholesterol requirements needed for cell growth, maintenance, steroids, and bile acids. LDLs release their contents to the cell after binding with LDL cell receptor sites specifically designed for this purpose. Cholesterol is internalized by the cell and it is at this point that feedback mechanisms inhibit the further production of cholesterol by the body (Schaefer & Levy, 1985). When the blood level of LDLs is higher than what the LDL cell receptor sites can accommodate, macrophages and other cells without receptor sites take them up. These cells have a lower affinity for LDLs than receptor site cells, but are important in clearing LDLs from the plasma when levels are high (Gagong, 1985).

The cycle continues with the transfer of free cholesterol to high density lipoproteins (HDLs) (Arky, 1984). HDLs, which contain the highest proportion of protein, are formed mainly in the liver and intestine and serve to promote cholesterol exchange and esterification. Cholesterol from HDLs is transferred to LDLs, IDLs and VLDLs (Gundy, 1984). They are important, also, in what is known as "reverse cholesterol transport", which assists the liver in catabolism of cholesterol (Gotto et al, 1984). Cholesterol thus delivered can be converted by the liver to bile acids which may be removed from the body in the feces (Hoeg et al, 1986).

Hyperlipidemia:

The overabundance of lipoproteins in the blood is termed hyperlipidemia, literally, excessive lipids in the blood, and can be categorized by the type

of lipoprotein found to be elevated. Hyperlipidemia (HLP) can result from either an overproduction of one of the lipoproteins or from a defect in its clearance.

Gotto and co-workers (1984) note that there appear to be three main causes of HLP: (1) genetic, or primary causes, (2) secondary causes resulting from disease states which affect clearance or production of lipoprotein components, and (3) dietary. Each of the principle lipoproteins may be elevated, though elevations of LDLs and VLDLs are the most common.

Frederickson, Levy, and Lees (1967) have classified elevations of lipoproteins according to phenotype as seen in Table 2. Type I is very rare, caused by a genetic defect in the lipoprotein lipase enzyme required to clear chylomicrons from the circulation. Types III and V are relatively uncommon and may be caused by primary or secondary factors (Haber and Kwiterovich, 1984). Types IIa, IIb and IV are the most common and appear to be caused by any one of the three factors identified by Gotto and co-workers (1984) or a combination of them (Gundy, 1984).

Type IV is most often diagnosed in adults and is due to elevated VLDL. Plasma triglycerides are the main lipoprotein component of VLDLs, cholesterol is normal to slightly elevated. Type IV HLP sometimes reflects a familial disorder transmitted by a dominant trait. Secondary disorders can cause an overproduction of triglycerides leading to raised VLDL levels; obesity exacerbates the condition (Bennion, 1980).

In Types IIa and IIb, LDL is the elevated lipoprotein. LDL is most closely associated with plasma cholesterol levels and CHD and may affect up to

TABLE 2

PHENOTYPE CLASSIFICATIONS FOR HYPERLIPIDEMIA AND THEIR INCIDENCE

| PHENOTYPE | PLASMA LIPOPROTEIN PRESENT IN EXCESS | INCIDENCE |
|---|---|---|
| I | Chylomicrons | Very rare |
| IIa | LDL | Common |
| IIb | LDL & VLDL | Common |
| III | Beta VLDL | Relatively common |
| IV | VLDL | Common |
| V | Chylomicrons & VLDL | Uncommon |

Note. Adapted from "Dyslipoproteinemias and xanthomatosis" by C. Haber and P. O. Kwiterovich, 1984, Pediatric Dermotology, 1, p. 268. 

60% of the adult population (Gotto et al, 1984). Elevations appear to be caused by genetic defects for the production of LDL receptor sites on the cells (Gundy 1986), untreated secondary causes such as hypothyroidism, diabetes mellitus, and biliary obstruction (Gagong, 1985), and obesity, high dietary fat, and cholesterol intake (Gotto et al, 1984).

It is interesting to note that many of the HLP types have primary or secondary causes. Hoeg and co-workers (1986) however, note that the majority of hyperlipidemic patients manifest primary rather than secondary HLP.

Cholesterol Levels and CHD:

With such a high proportion of the adult population possessing genetic traits and risk factors for the development of CHD, Hoeg and co-workers (1986) recommend that virtually all patients be screened for hyperlipoproteinemia during routine physical examinations.

An examination may reveal a xanthoma, a yellowish deposit of lipid material on the knees, heels, elbows, hands, etc. (Haber and Kwiterovich, 1984). A family medical history can alert the physician to a particular medical problem if close relatives have shown a disposition for heart disease or atherosclerosis (Hoeg et al, 1986). The high rates of CHD in patients with elevated cholesterol (LDL) leaves little doubt that it should be treated but the level at which it should be treated and the modality for treatment are not concrete.

Research has shown that as plasma cholesterol levels rise, the risk of developing CHD accelerates. The relationship has proven to be curvilinear,

thus as the cholesterol level goes up, the risk of developing CHD greatly increases (Gotto et al, 1984). CHD is common in countries where the average plasma cholesterol is above 200 mg/dl, such as in North America, Europe and Australia. When cholesterol is at or below 150 mg/dg (as in the Far East), the prevelance of atherosclerosis is less frequent. Gotto and co-workers (1984) state "the risk of CHD more than doubles when cholesterol levels double (p. 1068A)."

What constitutes a high cholesterol level in the plasma seems to vary from one researcher to another. There are no definite cut points which define risk categories (Marwick, 1986) but in general, plasma cholesterol levels above the 90th percentile are considered to be high risk (Hoeg et al, 1986; Pepper, 1986). Others place it slightly higher, at 95% (HHS, 1986) (see Table 3, which depicts age, percentile and cholesterol level).

Another way to classify cholesterol levels is according to "quintiles" which were described by the Pooling Project on the relationship of blood pressure, serum cholesterol and other risk factors for the development of CHD (Gotto et al, 1984). Cholesterol levels were grouped into five incremental categories (Table 4) with quintile V and above constituting high risk. Moderate risk in this model falls into Levels III and IV with minimal risk occurring in Levels I and II.

Gotto and co-workers (1984) admit to the difficulty in determining what constitutes a high cholesterol level. Obviously age, sex, obesity and other

TABLE 3

PLASMA TOTAL CHOLESTEROL (mg/dl)

(POPULATION DISTRIBUTION)

White Males
Percentiles

| AGE | 5 | 10 | 25 | 50 | 75 | 90 | 95 |
|---|---|---|---|---|---|---|---|
| 5-9 | 125 | 131 | 141 | 153 | 168 | 183 | 189 |
| 10-14 | 124 | 131 | 144 | 160 | 173 | 188 | 202 |
| 15-19 | 118 | 123 | 136 | 152 | 168 | 183 | 191 |
| 20-24 | 118 | 126 | 142 | 159 | 179 | 197 | 212 |
| 25-29 | 130 | 137 | 154 | 176 | 199 | 223 | 234 |
| 30-34 | 142 | 152 | 171 | 190 | 213 | 237 | 258 |
| 35-39 | 147 | 157 | 176 | 195 | 222 | 248 | 267 |
| 40-44 | 150 | 160 | 179 | 204 | 229 | 251 | 260 |
| 45-49 | 163 | 171 | 188 | 210 | 235 | 258 | 275 |
| 50-54 | 157 | 168 | 189 | 211 | 237 | 263 | 274 |
| 55-59 | 161 | 172 | 188 | 214 | 236 | 260 | 280 |
| 60-64 | 163 | 170 | 191 | 215 | 237 | 262 | 287 |
| 65-69 | 166 | 174 | 192 | 213 | 250 | 275 | 288 |
| 70+ | 144 | 160 | 185 | 214 | 236 | 253 | 265 |

White Females
Percentiles

| AGE | 5 | 10 | 25 | 50 | 75 | 90 | 95 |
|---|---|---|---|---|---|---|---|
| 5-9 | 131 | 136 | 151 | 164 | 176 | 190 | 197 |
| 10-14 | 125 | 134 | 142 | 159 | 171 | 191 | 205 |
| 15-19 | 118 | 126 | 140 | 157 | 176 | 198 | 207 |
| 20-24 | 121 | 132 | 147 | 165 | 186 | 220 | 237 |
| 25-29 | 130 | 142 | 158 | 178 | 198 | 217 | 231 |
| 30-34 | 133 | 141 | 158 | 178 | 199 | 215 | 228 |
| 35-39 | 139 | 149 | 165 | 186 | 209 | 233 | 249 |
| 40-44 | 146 | 156 | 172 | 193 | 220 | 241 | 259 |
| 45-49 | 148 | 162 | 182 | 204 | 231 | 256 | 268 |
| 50-54 | 163 | 171 | 188 | 214 | 240 | 267 | 281 |
| 55-59 | 167 | 182 | 201 | 229 | 251 | 278 | 294 |
| 60-64 | 172 | 186 | 207 | 226 | 251 | 282 | 300 |
| 65-69 | 167 | 179 | 212 | 233 | 259 | 282 | 291 |
| 70+ | 173 | 181 | 196 | 226 | 249 | 268 | 280 |

Note: From "Recommendations for treatment of hyperlipidemia in adults: A joint statement of the nutrition committee and the council on arteriosclerosis" by A. M. Gotto, E. L. Bierman, W. E. Connor, C. H. Ford, I. D. Frantz, C. J. Glueck, S.M. Grundy, and J. A. Little, 1984, Circulation 69, p. 1070A.

TABLE 4

PLASMA CHOLESTEROL QUINTILES

| QUINTILE | CHOLESTEROL LEVEL |
|---|---|
| I | $\leq$194 mg/dl |
| II | 195 mg/dl - 218 mg/dl |
| III | 219 mg/dl - 240 mg/dl |
| IV | 241 mg/dl - 268 mg/dl |
| V | 268 mg/dl$\geq$ |

Note: From "Recommendations for treatment of hyperlipidemia in adults: A joint statement of the nutrition committee and the council on arteriosclerosis" by A. M. Gotto, E. L. Bierman, W. E. Connor, C. H. Ford, I. D. Frantz, C. J. Glueck, S.M. Grundy, and J. A. Little, 1984, Circulation 69, p. 1070A.

risk factors need to be considered when treatment is contemplated. They use a cut point of 95% by age and sex as the parameter for classifying high cholesterol.

Table 5 lists risk factors for atherosclerosis. The majority of the population under 65 years of age exhibit at least one risk factor (Petersdorf, et al, 1983). The risk factor concept implies that a person with at least one risk factor will have a greater chance of developing atherosclerosis; multiple risk factors accelerate the process. However, as noted in the table, several risk factors are reversible and can be medically dealt with in order to control CHD development.

Age, sex, and genetic traits are irreversible, but those traits found to be the most "potent" for CHD, also are the traits which health care providers can focus their therapeutic efforts (Petersdorf et al, 1983; Hoeg et al, 1986; Schaefer & Levy, 1986).

Treatment Recommendations:

The first step in any treatment plan for reducing HLP and CHD is to initiate a diet program. This should include achieving ideal body weight (see Table 6) and instruction on dietary sources of fat and cholesterol (Petersdorf et al, 1983; Gotto et al, 1984; Gagong, 1985; Hoeg et al, 1986). Aerobic exercise should be encouraged within the patient's abilities and smoking should be eliminated (Hoeg et al, 1986).

Drug therapy should be initiated only after diet therapy has been tried and evaluated for effectiveness. In cases of extremely high cholesterol

TABLE 5

RISK FACTORS FOR ATHEROSCLEROSIS

1 NOT REVERSIBLE

- a Aging
- b Male sex
- c Genetic traits--positive family history of premature atherosclerosis

2 REVERSIBLE

- a Cigarette smoking
- b Hypertension
- c Obesity

3 POTENTIALLY OR PARTIALLY REVERSIBLE

- a Hyperlipidemia--hypercholesterolemia and/or hypertriglyceridemia
- b Hyperglycemia and diabetes mellitus
- c Low levels of high-density lipoproteins (HDL)

4 OTHER POSSIBLE FACTORS

- a Physical activity
- b Emotional stress and/or personality type

Note: From Harrison's Principles of Internal Medicine, R. G. Petersdorf, R. D. Adams, E. Brawnwald, K. J. Isselbacher, J. B. Martin, and J. D. Wilson, editors, 1983, New York: McGraw-Hill.

TABLE 6

IDEAL WEIGHT

IDEAL WEIGHT

| MEN | | | | WOMEN | | | |
|---|---|---|---|---|---|---|---|
| HEIGHT | SMALL FRAME | MEDIUM FRAME | LARGE FRAME | HEIGHT | SMALL FRAME | MEDIUM FRAME | LARGE FRAME |
| 5'2" | 128 - 134 | 131 - 141 | 138 - 150 | 4'10" | 102 - 111 | 109 - 121 | 118 - 131 |
| 5'3" | 130 - 136 | 133 - 143 | 140 - 153 | 4'11" | 103 - 113 | 111 - 123 | 120 - 134 |
| 5'4" | 132 - 138 | 135 - 145 | 142 - 156 | 5'0" | 104 - 115 | 113 - 126 | 122 - 137 |
| 5'5" | 134 - 140 | 137 - 148 | 144 - 160 | 5'1" | 106 - 188 | 115 - 129 | 125 - 140 |
| 5'6" | 136 - 142 | 139 - 151 | 146 - 164 | 5'2" | 108 - 121 | 118 - 132 | 128 - 143 |
| 5'7" | 138 - 145 | 142 - 154 | 149 - 168 | 5'3" | 111 - 124 | 121 - 135 | 131 - 147 |
| 5'8" | 140 - 148 | 145 - 157 | 152 - 172 | 5'4" | 114 - 127 | 124 - 138 | 134 - 151 |
| 5'9" | 142 - 151 | 148 - 160 | 155 - 176 | 5'5" | 117 - 130 | 127 - 141 | 137 - 155 |
| 5'10" | 144 - 154 | 151 - 163 | 158 - 160 | 5'6" | 120 - 133 | 130 - 144 | 140 - 159 |
| 5'11" | 146 - 157 | 154 - 166 | 161 - 184 | 5'7" | 123 - 136 | 133 - 147 | 143 - 163 |
| 6'0" | 149 - 160 | 157 - 170 | 164 - 188 | 5'8" | 126 - 139 | 136 - 150 | 146 - 167 |
| 6'1" | 152 - 164 | 160 - 174 | 168 - 192 | 5'9" | 129 - 142 | 139 - 153 | 149 - 170 |
| 6'2" | 155 - 168 | 164 - 178 | 172 - 197 | 5'10" | 132 - 145 | 142 - 156 | 152 - 173 |
| 6'3" | 158 - 172 | 167 - 182 | 176 - 202 | 5'11" | 135 - 148 | 145 - 159 | 155 - 176 |
| 6'4" | 162 - 176 | 171 - 187 | 181 - 207 | 6'0" | 138 - 151 | 148 - 162 | 158 - 179 |

Note: From 1979 Build Study (1980) Society of Actuaries and Association of Life Insurance Medical Directors of America.

levels, drug and diet therapy may be initiated at the beginning of treatment (Pepper, 1986). In any case, diet therapy should continue whether medications are used or not. Pepper (1986) warns that no direct evidence for the safety of any cholesterol lowering drug when given over decades is yet available. Diet therapy appears to be the safest method of treatment and certainly causes no harm (Gotto et al, 1984).

The American Heart Association recommends a three phase dietary program that can be used to reduce dietary cholesterol. It is outlined as follows:

Phase I - The diet should be composed of

| | |
|---|---|
| Fat | 30% |
| Carbohydrates | 55% |
| Protein | 15% |

Complex carbohydrates should be the main source of total carbohydrates. Fats should be saturated, polyunsaturated and mono-unsaturated, each contributing about 10% of total calories. This will contribute a cholesterol intake of approximately 300 mg per day.

Phase II

| | |
|---|---|
| Fat | 25% |
| Carbohydrates | 60% |
| Protein | 15% |

Dietary fat is reduced but should be made up of mono-unsaturated fats, polyunsaturated fats, and saturated fats. This will provide 200-250 mg of cholesterol per day.

Phase III

| | |
|---|---|
| Fat | 20% |
| Carbohydrates | 65% |
| Protein | 15% |

Equal amounts of the three types of fat should be included in the fat portion of the diet. A total of 100-150 mg of cholesterol should be derived from such a diet plan (AHA, 1978).

All patients may be started out at Phase I. This type of nutrient breakdown can be met with calorie levels between 1200-1500 and will provide adequate amounts of minerals and vitamins (Gotto et al, 1984). The lower calorie levels are conducive to weight loss which has been shown to have positive effects on lowering cholesterol, blood pressure and obesity (La Rosa, Goor, and Haines, 1986).

After an evaluation period of three to six months in which diet has been the only treatment modality (Hoeg et al, 1986), total cholesterol should be reevaluated. Phase II or III may be recommended if cholesterol continues to

remain high (HHS, 1986). Drug therapy also may begin at this time, but it should not replace diet modifications (La Rosa et al, 1986).

It is important to note that while diet modification is one of the prime therapeutic recommendations for treating HLP, the mere presentation of a diet to a patient will likely not result in a significant drop in total cholesterol or weight. Diet restriction coupled with exercise training and behavior modification have been shown to be much more successful than diet teaching alone in lowering cholesterol levels (Heath and Broadhurst, 1984; Foreyt, Scott, Mitchell and Gotto, 1979).

Vickery and Hodges (1986) address the issue of providing information and becoming involved in behavior modification from the dietitian standpoint. They make a distinction between nutrition education and nutrition counseling, defining nutrition education to be simply the delivery of information and facts. Nutrition counseling calls for direct involvement in goal setting, tailoring the information to individual needs, selecting options, and reinforcing appropriate behavior. Behavior modification is the approach recommended for nurse practitioners when working with obese patients for weight loss (White, 1986).

Foreyt and co-workers (1979) have found that a behavior modification/nutrition education combination to be more effective than simple nutrition education programs in reducing cholesterol.

Their study compared the effectiveness of three types of intervention, diet booklet only, nutrition education only, and behavior

modification/nutrition education, in reducing plasma cholesterol and triglycerides. But, while the behavior modification group showed the most significant cholesterol reduction at six months, all groups began to show increases in cholesterol from their low points by the twelveth month after the study. Thus, compliance becomes an issue for the health care worker when consulting hyperlipidemic patients.

Compliance:

"Noncompliance may be the most significant problem facing medical practice today" (Eraker, Kirscht, and Becker, 1984, p. 258). For while health care providers may explain the therapy, take detailed history, and outline the benefits of the compliance, patients fail to follow through more often than not. This is especially true whenever some form of self-administration or discretionary action is involved on the part of the patient (Becker, 1985).

Becker (1985) suggests that in developing a treatment regimen, specific steps be taken in order to increase adherence. The plan should be prioritized, emphasizing implementation in an incremental fashion rather than delivering the entire instruction and expecting the patient to be responsible for the results. The plan should be a progression from one stage to another, with successful completion or noticeable progress in the earlier stages before moving on to more difficult parts of the plan. Therapy requiring lifestyle changes such as diet, exercise and smoking cessation should be introduced over the course of several visits.

## METHODOLOGY

The sample size for the study was determined by using the following mathematical formula (Daniel, 1983).

$$n = \frac{Nz^2 pq}{d^2 (N-1) + Z^2 pq}$$

where n = the study sample.

N = population size.

z = the desired Z statistic.

p = the proportion possessing hyperlipoproteinemia in the population.

q = the proportion of the population not possessing hyperlipoproteinemia.

d = the desired width of the difference of the true population, or confidence interval.

The population supported by Irwin Army Community Hospital was determined to be 67,482 as of October 1, 1986. This population is comprised of active duty military members, their dependents, retired military members, and their dependents. The majority of this population lives in Kansas, principally in Geary and Riley counties. The remainder lives in Nebraska and the Dakotas.

The desired z statistic was 1.96 which corresponds to a 95 percent confidence interval. The proportion of the general population possessing hyperlipoproteinemia, particularly familial hypercholesterolemia, is dependent upon how hypercholesterolemia is defined. Some researchers define a blood

cholesterol level above 240 mg/dl as the cut point and estimate approximately 20-25% of the population is affected (Blank, Hoeg, Kroll and Ruddel, 1986; Gundy, 1986; Marwick, 1986), but most researchers agree that a cholesterol level below 200 mg/dl is a desirable level. It is estimated that approximately 50-60% of the population is above this level (HHS, 1986; Gotto et al, 1984).

Because a precise proportion could not be determined based on review of the literature a p value of 0.5 was be used. The q value was 0.5 also (q = 1 - p = 0.5). This will yield the maximum value for n (Daniel, 1983) while using the Health and Human Services (1986) figure of the population affected with hypercholesterolemia.

The final value, the confidence interval or d value, was set at d = 0.15. Restating the equation with the values yields an n

$$n = \frac{(67{,}482\ (1.96)^2\ (0.50)\ (0.50)}{(0.15)^2\ (67{,}482-1) + (1.96)^2(0.50)\ (0.50)}$$

$$n = 42.65$$

or 43 individual subjects; 22 per health care provider.

Daniel (1983) suggests that "when N is large in comparison to n (that is, $n/N \leq 0.05$), the finite population correction (making use of N) may be ignored" (p. 146). This renders the following equation:

$$n = \frac{Z^2\ pq}{d^2}$$

which gives the same value for n as the longer equation.

In this project, the N value was used because the n value was unknown. In either case, the final n value is the same.

The sampling conducted for this study was from a large population without replacement. It can be reasonably assumed that this population is normally distributed, but in order to assure normal distribution, the sample size was increased by ten for each health care provider for a total 32 individuals each, or 64 in all.

The advantage of having each health care provider see at least 30 individuals is that even if the population is not normally distributed, the sample will "guarantee . . . approximately the same results as would be obtained if the [population was] normally distributed" provided that a large sample is taken (Daniel, 1983, p. 102).

A large sample size is one of at least 30. This is what is known as the central limit theorem (Daniel, 1983).

Selection of Volunteers:

The subjects for the study were selected in the following way:

Subjects were selected at random from among patients seen in the Department of Primary Care and Community Medicine and in the Department of Medicine. Within these two departments are the following specialties: Physical Examination, Family Practice, General Medial Outpatient Clinic, Emergency Treatment Center, Troop Medical Clinics, Dermatology, and Internal Medicine. These specialties come in contact with nearly all patients entering the hospital.

Physicians in these clinics commonly order chemical profiles of the blood which give the results of parameters such as albumen, blood glucose, total protein, and total cholesterol. Normally six to twelve parameters are requested and analyzed on a Sequential Multiple Analyser (SMA). Thus, the SMA 12 indicates twelve diagnostic parameters analyzed from a sample of blood.

The laboratory section normally batch processes all SMA requests and makes three copies. A copy goes to the physician, the patient's medical record, and the laboratory archive. The archive is maintained as a back-up for misplaced results from the other two.

The archive provided the initial screening data required to select potential volunteers. SMA 12 reports were screened according to the criteria for the study. Laboratory results meeting the criteria were noted and then discussed with the physician who had requested the test. In every case, the test had been requested for reasons other than hyperlipidemia. Physicians were asked to consider the patients in light of the secondary causes of hyperlipidemia (Table 7). Patients having no secondary causes for mild hyperlipidemia were approved by the physician for participation in the study providing they agreed to participate.

Patients were contacted and asked to participate in the study for the purpose of treating mild hyperlipidemia. All those agreeing to participate were presented with a Volunteer Agreement Affidavit, Department of the Army Form 5303-R (Army Regulation 40-38, 1984) (Figure 3) and a consultation sheet, Standard Form 513 (Figure 4).

TABLE 7

CAUSES OF SECONDARY HYPERCHOLESTEROLEMIA

Hypothyroidism

Nephrotic Syndrome

Dysproteinemias

Obstructive Liver Disease (lipoprotein X)

Thiazide Diuretics

Note: From "Recommendations for treatment of hyperlipidemia in adults: A joint statement of the nutrition committee and the council on arteriosclerosis" by A. M. Gotto, E. L. Bierman, W. E. Connor, C. H. Ford, I. D. Frantz, C. J. Glueck, S.M. Grundy, and J. A. Little, 1984, Circulation 69, p. 1070A.

FIGURE 3

## VOLUNTEER AGREEMENT AFFIDAVIT

For use of this form, see AR 40-38; the proponent agency is the Office of the Surgeon General

THIS FORM IS AFFECTED BY THE PRIVACY ACT OF 1974

1. AUTHORITY: 10 USC 3012, 44 USC 3101 and 10 USC 1071-1087.

2. PRINCIPAL PURPOSE: To document voluntary participation in the Clinical Investigation and Research Program. SSN and home address will be used for identification and locating purpose.

3. ROUTINE USES: The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study, implementation of medical programs, teaching; adjudication of claims, and for the mandatory [illegible]

4. MANDATORY OR VOLUNTARY DISCLOSURE: **The furnishing of SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this investigational study.**

### PART A - VOLUNTEER AFFIDAVIT

VOLUNTEER SUBJECTS IN APPROVED DEPARTMENT OF THE ARMY RESEARCH STUDIES

Volunteers under the provisions of AR 70-25 are authorized all necessary medical care for injury or disease which is the proximate result of their participation in such studies.

I, _____ SSN _____ having
*(last, first, middle)*

full capacity to consent and having attained my _____ birthday, do hereby volunteer to participate in

an inquiry into differences in patient outcomes by observing dietitian and nurse practitioner management of hyperlipidemia.
*(research study)*

under direction of CPT Thomas B. Bullen conducted at Irwin Army Community Hospital
*(name of institution)*

The implications of my voluntary participation; the nature, duration and purpose of the research study; the methods and means by which it is to be conducted; and the inconveniences and hazards that may reasonably be expected have been explained to me by CPT Thomas B. Bullen

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights on study-related injury I may contact CPT Thomas B. Bullen

at Irwin Army Community Hospital, Bldg 485, Fort Riley, KS 66442-5037 (913) 239-7146
*(name and address of hospital & phone number (include area code))*

I understand that I may at any time during the course of this study revoke my consent and withdraw from the study without further penalty or loss of benefits however, I may be ☐ required *(military volunteer)* or ☐ requested *(civilian volunteer)* to undergo certain examination if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

### PART B - TO BE COMPLETED BY INVESTIGATOR

INSTRUCTIONS FOR ELEMENTS OF INFORMED CONSENT: (Provide a detailed explanation in accordance with Appendix E, AR 40-38 or AR 70-25.)

Patients found to be at moderate risk for development of coronary heart disease (CHD) due to elevated total cholesterol will be asked to see either a dietitian or nurse practitioner at Irwin Army Community Hospital. These health care providers will instruct the patient on dietary control of cholesterol.

Appointments will be made according to patient need as determined by the health care provider. Participation in the study will not require a great deal of time at the hospital on the part of the patient. Military members will not be required to be away from work for lengthy periods of time.

At the end of 120 days (4 months) each volunteer will return to the General Medical Outpatient Clinic at Irwin Army Community Hospital for a blood test to determine total cholesterol. Differences in total cholesterol at the end of the study will be compared to levels at the beginning of the study. Volunteers may obtain a full disclosure of the results of the study upon request.

(CONTINUE ON REVERSE)

DA FORM 5303-R, APR 84

Figure 3 (continued)

PART B - TO BE COMPLETED BY INVESTIGATOR

Approximately sixty (60) volunteers will participate in the study. No particular precautions or risks to health will be caused by participating in this study.

| SIGNATURE OF VOLUNTEER | DATE SIGNED | SIGNATURE OF LEGAL GUARDIAN (if a minor) |
|---|---|---|
| PERMANENT ADDRESS OF VOLUNTEER | TYPED OR PRINTED NAME AND SIGNATURE OF WITNESS | DATE SIGNED |

FDA FORM 3303 (4/84)

☆ U.S. G.P.O. 1983-392-154

FIGURE 4

| MEDICAL RECORD | CONSULTATION SHEET | |
|---|---|---|
| **REQUEST** | | |
| TO: | FROM: *(Requesting physician or activity)* | DATE OF REQUEST |

REASON FOR REQUEST *(Complaints and findings)*

Please assist this patient with cholesterol reduction. Cholesterol moderately elevated at _____ mg/dl. Please record present body weight.

PROVISIONAL DIAGNOSIS

| DOCTOR'S SIGNATURE | APPROVED | PLACE OF CONSULTATION | ☐ ROUTINE ☐ TODAY |
|---|---|---|---|
| | | ☐ BEDSIDE ☐ ON CALL | ☐ 72 HOURS ☐ EMERGENCY |

**CONSULTATION REPORT**

*(Continued on reverse side)*

| SIGNATURE AND TITLE | | | DATE |
|---|---|---|---|
| IDENTIFICATION NO. | ORGANIZATION | REGISTER NO | WARD NO |

PATIENT'S IDENTIFICATION *(For typed or written entries give: Name—last, first, middle; grade; rank; race; hospital or medical facility)*

**CONSULTATION SHEET**
**STANDARD FORM 513** (Rev 9-77)
Prescribed by GSA/ICMR
FPMR 101-11.808-8
513-107

The consultation form was signed by the volunteer's physician addressed to the health care provider. Volunteers were asked to make their own appointments. This emulated the usual procedure for patient contact with providers at Irwin Army Community Hospital.

Volunteers selected during the months of October and November, 1986 were referred to the nurse practitioner for treatment. Those selected during December, 1986 and January, 1987 were referred to the dietitian. A total of 66 volunteers agreed to participate in the study - 33 per health care provider.

## TREATMENT

The nurse practitioner followed a care plan which included physical assessment, diet, exercise, counseling, smoking cessation, and treatment of other CHD risk factors (see Appendix A). Several patients were identified as hypertensives and were treated for that condition in addition to cholesterol reduction. This additional intervention should not have affected cholesterol reduction.

Diet was the major thrust of intervention with volunteers assigned to the dietary service. Diet histories were taken and smoking habits were recorded. Those indicating a smoking habit were given literature on smoking and heart disease but no mention of the risk factors of smoking in CHD were recorded in patient records.

A diet which controlled saturated fat and cholesterol intake was explained (see Appendix B). Weight reduction was not specifically addressed by the dietitian due to the nature of the consulation request. Weight status was recorded as requested and comparison to ideal body weight was made.

## RESULTS

The study concluded with 59 of 66 volunteers having made appointments with the health care provider and completing the second blood test. Thus, 89 percent of the volunteers completed the study.

The nurse practitioner consulted with 31 of the volunteers, 29 of whom finished the study. Two volunteers could not be contacted for the final blood test and two failed to make an initial appointment.

The dietitian consulted with 32 volunteers, 30 of whom finished the study. One volunteer failed to make an initial appointment; one was not available for the final blood test; one volunteer did not make an appointment until March, 1987, which meant collection of the final data would not occur until July, 1987. This volunteer was dropped from the data collection for this study.

Information regarding when initial appointments with the health care provider had been held was obtained by reviewing central appointment records and patient medical records. A period of four months was then projected for each individual volunteer.

At the end of the four month period, volunteers were contacted and requested to undergo a final, fasting blood test to determine cholesterol levels. Those volunteers having a fasting blood test at the four month interval as part of the treatment provided by the nurse practitioner were not requested to undergo another blood test.

Twenty five of the 29 volunteers seen by the nurse practitioner were thus treated. The remaining four volunteers were contacted by the investigator in order to complete the blood test.

Blood tests were analyzed by the SMA-12 as before. Results of the two groups are shown in Tables 8 and 9. The tables show age, sex, cholesterol before the health care provider intervention, cholesterol level after intervention, and the number of visits made by the volunteer to the health care provider. The upper limit of ideal body weight was noted. Smoking behavior, when it was recorded by the health care provider, was noted as well as exercise behavior.

In Table 8, exercise was assigned a numerical value in order to facilitate analysis. Values were given according to nurse practitioner designations, a "1" being equal to sedentary, "2" being equal to moderate activity, and "3" being equal to very physically active.

Overweight status was determined by comparing weights before and after treatment to the ideal body weight standards. Yes and No designations were assigned.

Cholesterol change and weight change are last. Positive values indicate an increase in cholesterol or weight from beginning to end of the study. Negative values indicate a weight or cholesterol reduction.

Missing values in ideal body weight categories, smoking, and exercise were due to missing information not recorded by the nurse practitioner and dietitian.

Table 9 shows the results of volunteers seen by the dietitian. The dietitian made no assessment of exercise behavior but did record smoking

TABLE 8

PATIENT VOLUNTEERS TREATED BY THE NURSE PRACTITIONER

| | AGE | SEX | CHOLB | CHO.A | WTB | WTA | VISITS | IBW | SMOKES | SMOKEA | EXERB | EXERA | OVERWGTB | OVERWGTA | CHOLCHG | WTCHG |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | 74 | F | 285 | 302 | 172 | 185 | 3 | 139 | | | 1 | | Y | Y | 17 | 13 |
| 2. | 55 | M | 278 | 227 | 162 | 158 | 3 | 166 | | | | | M | M | -51 | -4 |
| 3. | 62 | M | 74 | 273 | 173 | 165 | 3 | 176 | M | M | 2 | 2 | M | M | -1 | -8 |
| 4. | 36 | M | 221 | 200 | 261 | 254 | 2 | 158 | | | 2 | 2 | Y | Y | -21 | -7 |
| 5. | 61 | F | 225 | 210 | 189 | 199 | 2 | 156 | | | | 1 | Y | Y | -15 | 10 |
| 6. | 62 | F | 235 | 281 | 146 | 150 | 1 | 150 | | | 2 | 2 | M | M | 46 | 4 |
| 7. | 66 | M | 274 | 263 | | 157 | 2 | 162 | | | | | | M | -11 | |
| 8. | 63 | F | 241 | 240 | 222 | 222 | 2 | 139 | | | 1 | 1 | Y | Y | -1 | 0 |
| 9. | 49 | F | 222 | 253 | 129 | 139 | 3 | 139 | | | | | M | M | 31 | 10 |
| 10. | 55 | F | 271 | 254 | 140 | 141 | 3 | 139 | | Y | | | M | M | -17 | 1 |
| 11. | 54 | F | 237 | 266 | 146 | 149 | 2 | 142 | | Y | 1 | | M | M | 29 | 3 |
| 12. | 60 | F | 258 | 260 | 159 | 162 | 3 | 136 | | | 1 | 1 | Y | Y | 2 | 3 |
| 13. | 46 | M | 255 | 255 | 174 | 169 | 2 | 158 | Y | Y | | | Y | M | 0 | -5 |
| 14. | 46 | F | 257 | 250 | 170 | 171 | 2 | 139 | Y | Y | 1 | 1 | Y | Y | -7 | 1 |
| 15. | 49 | M | 248 | 275 | 213 | 217 | 2 | 172 | Y | Y | 1 | 1 | Y | Y | 27 | 4 |
| 16. | 47 | F | 247 | 344 | 153 | 150 | 2 | 145 | | Y | 1 | 1 | M | M | 97 | -3 |
| 17. | 63 | F | 268 | 268 | 148 | 146 | 2 | 127 | | M | | 2 | Y | Y | 0 | -2 |
| 18. | 58 | F | 270 | 259 | 130 | 126 | 3 | 132 | | Y | 2 | | M | M | -11 | -4 |
| 19. | 56 | F | 252 | 272 | 185 | 183 | 2 | 162 | M | M | 1 | 1 | Y | Y | 20 | -2 |
| 20. | 67 | F | 240 | 298 | 189 | 196 | 2 | 153 | | | 1 | 1 | Y | Y | 58 | 7 |
| 21. | 59 | F | 268 | 281 | 155 | 155 | 1 | 139 | | | 1 | 1 | Y | Y | 13 | 0 |
| 22. | 50 | M | 250 | 251 | 260 | 283 | 2 | 166 | | | | 1 | Y | Y | 1 | 23 |
| 23. | 58 | M | 239 | 208 | 219 | 191 | 4 | 175 | | | 1 | 1 | Y | Y | -31 | -28 |
| 24. | 51 | M | 232 | 221 | 200 | 205 | 2 | 175 | | | | | Y | Y | -11 | 5 |
| 25. | 37 | M | 244 | 280 | 188 | 196 | 1 | 175 | M | M | 3 | 3 | Y | Y | 36 | 8 |
| 26. | 54 | M | 220 | 186 | 243 | | 2 | 180 | | | 1 | 2 | Y | | -34 | |
| 27. | 59 | M | 222 | 218 | 195 | 206 | 2 | 169 | | | 1 | 2 | Y | Y | -4 | 11 |
| 28. | 42 | M | 250 | 262 | 156 | 140 | 1 | 146 | Y | Y | 2 | 2 | Y | M | 12 | -16 |
| 29. | 53 | M | 257 | 201 | 209 | 214 | 2 | 175 | | M | 2 | 2 | Y | Y | -56 | 5 |

TABLE 9

PATIENT VOLUNTEERS TREATED BY THE DIETITIAN

| | AGE | SEX | CHOLB | CHO.A | WTB | WTA | VISITS | IBW | SMOKES | SMOKEA | EXERB | EXERA | OVERWGTB | OVERWGTA | CHOLCHG | WTCHG |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. | 66 | F | 286 | 287 | 165 | 163 | 1 | 149.5 | N | N | | | Y | Y | 1 | -2 |
| 2. | 60 | M | 283 | 202 | 202 | 192 | 1 | 158.0 | N | N | | | Y | Y | -81 | -10 |
| 3. | 38 | M | 264 | 245 | 235 | 227 | 1 | 176.0 | Y | Y | | | Y | Y | -18 | -8 |
| 4. | 49 | F | 274 | 265 | 135 | 138 | 1 | 139.0 | Y | | | | N | N | -9 | 3 |
| 5. | 37 | M | 268 | 243 | 196 | 192 | 1 | 172.0 | Y | Y | | | Y | Y | -25 | -4 |
| 6. | 58 | F | 274 | 313 | 160 | 158 | 1 | 151.5 | N | N | | | N | N | 39 | -2 |
| 7. | 40 | M | 250 | 227 | 189 | 207 | 1 | 162.0 | N | N | | | Y | Y | -23 | 18 |
| 8. | 62 | F | 249 | 253 | 152 | 138 | 1 | 150.0 | N | N | | | N | N | 4 | -14 |
| 9. | 44 | M | 248 | 263 | 358 | 329 | 3 | 194.0 | | | | | Y | Y | 15 | -29 |
| 10. | 39 | M | 240 | 239 | 187 | 190 | 1 | 165.5 | N | N | | | Y | Y | -1 | 3 |
| 11. | 57 | F | 250 | 243 | 139 | 137 | 1 | 156.0 | Y | Y | | | N | N | -7 | -2 |
| 12. | 62 | F | 274 | 266 | 160 | 155 | 2 | 136.0 | N | N | | | Y | Y | -8 | -5 |
| 13. | 62 | M | 273 | 288 | 199 | 188 | 1 | 166.0 | N | N | | | Y | Y | 15 | -11 |
| 14. | 54 | F | 276 | 234 | 151 | 143 | 1 | 156.0 | N | N | | | N | N | -42 | -8 |
| 15. | 65 | F | 229 | 197 | 124 | 115 | 1 | 151.0 | N | N | | | N | N | -32 | -9 |
| 16. | 66 | F | 285 | 289 | 187 | 179 | 1 | 156.0 | Y | N | | | Y | Y | 4 | -8 |
| 17. | 47 | M | 278 | 244 | 183 | 175 | 1 | 158.0 | N | N | | | Y | Y | -34 | -8 |
| 18. | 63 | M | 255 | 243 | 178 | 176 | 1 | 176.0 | N | N | | | Y | N | -12 | -2 |
| 19. | 53 | F | 279 | 288 | 129 | 126 | 1 | 140.0 | Y | Y | | | N | N | 9 | -3 |
| 20. | 54 | F | 270 | 218 | 167 | 153 | 1 | 155.0 | N | N | | | Y | N | -52 | -14 |
| 21. | 65 | F | 273 | 267 | 167 | 166 | 1 | 147.0 | Y | Y | | | Y | Y | -6 | -1 |
| 22. | 63 | M | 245 | 209 | 142 | 149 | 1 | 192.0 | Y | N | | | N | N | -36 | 7 |
| 23. | 40 | M | 255 | 230 | 183 | 169 | 1 | 164.0 | N | N | | | Y | Y | -25 | -14 |
| 24. | 63 | F | 243 | 308 | 110 | 106 | 1 | 137.0 | N | N | | | N | N | 65 | -4 |
| 25. | 57 | F | 279 | 278 | 197 | 190 | 1 | 163.0 | Y | Y | | | Y | Y | -1 | -7 |
| 26. | 61 | F | 292 | 296 | 140 | 135 | 1 | 137.0 | Y | N | | | Y | N | 4 | -5 |
| 27. | 61 | M | 276 | 270 | 236 | 216 | 1 | 184.0 | N | N | | | Y | Y | -6 | -20 |
| 28. | 44 | M | 259 | 260 | 260 | 262 | 1 | 197.0 | Y | Y | | | Y | Y | 1 | 2 |
| 29. | 68 | F | 270 | 234 | 130 | 132 | 1 | 140.0 | Y | | | | N | N | -36 | 2 |
| 30. | 59 | F | 277 | 246 | 140 | 136 | 1 | 151.0 | N | N | | | N | N | -31 | -4 |

behavior. Other parameters are the same as those noted by the nurse practitioner.

Weights from the beginning of the study were recorded by the health care provider. The nurse practitioner used a Health-O-Meter balance beam scale. Final weights taken at the time of the last blood test for each patient by the investigator were done on a Health-O-Meter digital scale located in the General Medical Outpatient Clinic at Irwin Army Community Hospital. Three pounds was subtracted for allowance of clothing weight. The dietitian and nurse practitioner did not record whether weights included clothing weights.

## DISCUSSION OF COMPUTATIONS

Initial results of the F test and least squares means test procedures led to the conclusion that there were statistically significant changes in cholesterol and weight based on the group the volunteer was in, the sex of the volunteer, and the number of visits made by the volunteer to the health care provider. Appendix C shows calculations and figures conducted to determine significance.

In evaluating the significance of cholesterol change, the group the volunteer participated in was statistically significant at p=0.0176. The sex of the individual was significant at p=0.0290.

Identifying the nurse practitioner treatment group as Group 1 and the dietitian treatment group as Group 2 and then conducting a least squares means test indicated that Group 1 had a cholesterol increase of 9.235 while Group 2 had a decreae of -16.357. These results were not graphed due to lack of a continuous variable such as age which was not a significant factor in this study.

Least squares means test of sex indicated that females in the study tended to increase cholesterol, 6.714, while males lowered cholesterol, -13.836. Adjusting for group and sex of the individual showed females in Group 1 went up in cholesterol, 9.235. Males were down, -4.478. Group 2 results indicated females down -9.520 and males down -23.149.

F test evaluation of weight change indicated that group and the number of visits were significant. Group was significant at p=0.006 and visits significant at p=0.075.

Least squares means test showed Group 1 increasing 3.699; Group 2 decreasing weight, -8.326. Breakdown of groups by sex indicated Group 2 males and females reducing weight, -8.635 and -8.016 respectively. Males and females in Group 1 increased 2.525 and 4.753 respectively. But, while visits were statistically significant, it was of questionable value since 32 of the 59 volunteers had only one appointment with the health care provider during the study. In Group 2, nearly all of the volunteers, 28 out of 30, saw the dietitian once.

A second analysis of the data was performed after adjusting the means by eliminating nonsignificant parameters (see Appendix D).

The group the volunteer participated in and the sex of the individual continued to be significant; group p=0.0424, sex p=0.0094. But adjusting the sex of the individual and their group affiliation was not significant, p=0.2913.

Least squares means test of cholesterol change by group, sex and group*sex indicated the following: Group 2 reduced cholesterol, -11.767 while Group 1 increased, 3.590. Males, as a group, reduced cholesterol, -14.027 while females as a group increased, 5.851. Group*sex least squares means indicated that Group 1 females increased in cholesterol 17.467. Group 1 males reduced cholesterol -10.286. Group 2 females reduced cholesterol, -5.767 and Group 2 males reduced cholesterol also, -17.769.

An F test of weight change which was adjusted for group, sex and group*sex indicated group was significant p=0.0139. The other parameters were not statistically signficant. Least squares means of these parameters revealed

that Group 1 increased slightly, 0.867. Group 2 decreased in weight, -5.364. Males as a whole reduced in weight -3.423. Females also went down, 1.075. Group*sex least squares means showed Group 1 females increasing 2.733. Group 1 males went down -1.00. Group 2 males and females went down, -5.846 and -4.882 respectively.

Other parameters which had been looked at were exercise and smoking behavior. The inconsistency of reporting instruction or progress in these areas on the part of the health care providers made analysis questionable because of the lack of data.

Graphic representation of means can be seen in Appendix D. Figure 1 shows that male volunteers went down in cholesterol and weight, -13.889 and -3.520 respectively. Females increased in cholesterol, 5.125 but reduced weight, -1.313.

Figure 2 shows how the two groups compared. Again, figures are computations of means. In Group 1, males and females showed an increase in cholesterol and weight, 4.069 and 1.079 respectively. Group 2 showed decreases in cholesterol and weight, -10.967 and -5.300 respectively.

Figure 3 illustrates mean changes in cholesterol and weight of males and females in Group 1. This group was managed by the nurse practitioner. Males went down in cholesterol, -10.286 and weight, -1.000. Females increased their cholesterol levels, 17.467 and weight, 2.733.

Group 2 results in Figure 4 show that calculated means for males and females indicate reductions in cholesterol and weight. Male cholesterol was reduced 17.769; weight was reduced -5.765. Female cholesterol levels in Group

2 went down -5.846 and weight, -4.882. The calculated means indicate that males as a grup were more successful than females. This held true when males and females in the two groups were compared also.

When looking at the means between groups, however, Group 1 increased in weight and cholesterol while Group 2 went down in both. Statistical analysis, therefore, leads to the conclusion that there was a difference between the group of volunteers managed for cholesterol reduction by the nurse practitioner and the group of volunteers managed for cholesterol reduction by the dietitian. The dietitian's group showed statistically significant changes in cholesterol and weight.

Inconsistent reporting of exercise habits on the part of the dietitian and of smoking and exercise habits on the part of the nurse practitioner made analysis of these parameters of little value. Help in these areas may have been provided but by not annotating medical records, it is assumed counseling for these habits was not given. Age and the number of visits to the health care provider were either not significant or had to be discounted due to questionable validity.

# DISCUSSION

Results of this study suggest that individuals with moderately elevated cholesterol levels receiving counseling from the dietitian had a statistically significant reduction in cholesterol. The group seen by the nurse practitioner had no statistically significant reduction. It may, therefore, be concluded that there is a difference in patient outcome when a disease state such as moderate hypercholesterolemia is managed by nurse practitioners and dietitians. These conclusions, however, merit some reflection concerning their meaning. While this study shows a significant difference in patients treated by the dietitian at Irwin Army Community Hospital, there are several factors which may have had a significant influence on the results; the number of providers observed, the regimen presented; patient compliance, and the time of year patients were studied.

It must be remembered that one dietitian and one nurse practitioner were observed in this study. Whether one was more charismatic or thorough in presenting the treatment plan to the patients is unknown. Becker (1985) notes that personnel rapport between patients and providers helps to enhance compliance to the regimen. Tailoring the regimen also strengthens compliance. Both health care providers seemed to individualize treatment. Differences were noted in the number of appointments with the provider and what was discussed. The number of visits was not significant for cholesterol reduction but was significant for weight loss. However, with so many patients having seen the dietitian only once, the reliability of this conclusion is questionable.

The dietitian relied on diet counseling as the sole modality of treatment. Smoking, while noted, was not addressed other than to provide a pamphlet regarding the subject. Exercise habits were not recorded. Food selection and preparation techniques were noted and were made the focus of intervention. During the single session held with each patient volunteer, the dietitian instructed them on food purchasing, portion control and ways to reduce fat during cooking. Medical records noted the patients indicated an understanding of the instruction.

The nurse practitioner's approach to hypercholesterolemia was multifaceted in nature. Besides diet counseling, medical records contained medical histories and comments on blood pressure, temperature, and pulse rate. The exercise habits of 17 of the patients were complete (17=58%). Six records (21%) had incomplete data and six records (21%) contained no mention of exercise. Smoking habits were less frequently recorded. Seven records (24%) contained information on smoking habits before and after the study. Five records (17%) had partial data. The remainder (59%) contained no information on the subject. Diet instructions (as noted in patient medical records) indicated fat sources had been discussed and that a 1500 calorie level for males had been prescribed; females were prescribed a 1200 calorie level.

Follow-up appointments were recommended for all patients. Only four failed to see the nurse practitioner more than once. SMA-12 reports (fasting) were ordered prior to the instruction. Cholesterol results were annotated in the records and discussed during the visit. Patient understanding of instructions was annotated in all the records. Yet, in spite of these measures, patients seen by the nurse practitioner were not as successful in

cholesterol reduction. Non-compliant behavior is a possible explanation for this finding.

Becker (1985) states that compliance is hindered by complex instructions. Adherence to a treatment regimen is less likely if it is of long duration, dependent on an alteration of lifestyle, inconvenient, or expensive. Self administration, such as diet restriction, is another factor which tends to lower compliance. Dietary compliance is generally poor (Glantz, 1979), especially if previous compliance resulted in no noticeable change.

The nurse practioner regimen for cholesterol treatment was more extensive than the dietitian treatment regimen. Noncompliance may have occurred more frequently because there were more demands placed on the volunteers. The dietitian did not place caloric restrictions on the patient, require lifestyle changes such as implementation of an individual exercise program or smoking cessation. Compliance may have been better because demands were fewer.

Nevertheless, literature concerning the treatment of hyperlipidemia supports the approach taken by the nurse practitioner; dietary restriction of fats, smoking cessation, and weight loss (Merz, 1986). Many experts agree that these should be tailored to the individual.

Another consideration as to the difference in outcomes could be in the time of year in which patients were treated. In order to randomly assign patients to a provider, it was decided that the first 33 volunteers would be referred to the nurse practitioner beginning in October 1986. After that number had been achieved, the next 33 volunteers were referred to the dietitian which began in December, 1986. Six of the 21 volunteers contacted prior to 31 December, 1986 saw the dietitian during that month. The remaining

15 contacted in December and all of those contacted after January 1987 were seen during January. The significance in this observation is that while the nurse practitioner's group was seen during November and December, 1986 (Thanksgiving and Christmas being associated with food), the dietitian's group, for the most part, was seen after the holiday season. Compliance may have been lower in the nurse practitioner's group because of this. Nothing concerning this observation was detected by the nurse practitioner and annotated in the records.

# CONCLUSION

The results of this study would lend support to arguments by dietitians that their contributions to health care are significant and that their specialization is needed in the hospital setting. Administrators of small to medium-size hospitals may derive the most benefit from these results because it is likely that only one provider (dietitian and nurse practitioner) will be present in their respective services to render treatment.

The conclusions of this tudy should not be construed as calling for the elimination of services provided by either provider examined but serve to show that dietitians have an important role to play in the delivery of health care.

## APPENDIX A

## NURSE PRACTITIONER CHOLESTEROL TREATMENT PROTOCOL

SUBJECTIVE

A. Symptoms.

1. *Pain from tendon xanthomas.*

2. Recurrent abdominal pain.

B. Diet.

C. Exercise.

D. Medications.

E. Family History.

1. Hypertension, diabetes mellitus, coronary heart disease, cerebral vascular accident.

2. Family history of lipid disorders could be useful in diagnosis of familial hypercholesterolemia associated with very high risk of CHD.

F. Presence of other risk factors/possible secondary causes:

1. Diabetes mellitus, hypothyroidism.

2. Hypertension.

3. Cigarette smoking.

OBJECTIVE

A. Physical exam may inlude:

1. Blood pressure.

2. Pulse.

3. Height and weight.

4. Heart.

5. Bruits - carotid, renal, femural.

6. Palpitation of liver/spleen.

7. Skin - tendon xanthomas, xanthelasmas.

8. Funduscopic - lipemia retinalis.

B. Lab Data.

1. Initial screen.

a. Fasting total serum cholesterol.

b. If fasting, cholesterol above 75th percentile repeat with explicit instructions for 14-hour fast.

2. Initial screen + for HLP.

a. Fasting SMA-12.

b. Triglycerides.

c. HDL level.

d. Complete blood count.

e. Routine urinalysis.

f. Electrocardiogram.

C. Calculated lipid profile.

1. VLDL = triglycerides - 5.

2. LDL = total cholesterol - (HLD + VLDL).

ASSESSMENT

A. Secondary causes.

B. Primary HLP.

1. Type.

2. Risk (moderate, high).

a. Risk is high if any of the following exist:

1) Total cholesterol> 90th percentile.

2) LDL > 90th percentile.

3) HDL > 5th percentile.

4) Triglycerides > 1000 (high risk for pancreatitis).

PLAN

A. If secondary cause identified, treat secondary cause. Treatment of secondary cause will often resolve lipid abnormality.

B. If secondary cause eliminated or ruled out, then go to appropriate algorithm (Tables 3 and 4).

1. Elevated LDL, go to Table A.

2. Elevated triglycerides or VLDL, go to Table B.

C. Family screening: Recommend that patients with primary HLP encourage their blood relatives to be screened for HLP as well as to identify familial forms of HLP.

D. Diet.

1. Decreased intake of total cholesterol and saturated fats is the mainstay of treatment.

2. All patients considered to be high risk HLP should be referred to diet clinic for counseling.

3. Moderate risk HLP patients may benefit from informal counseling on reducing total fat intake. See Table 1.

E. Weight Loss. Patients should be encouraged to attain ideal body weight through regular exercise and moderation of intake.

F. Reduce or eliminate ETOH intake.

G. Patient Education. Patients should be counseled regarding risks of elevated serum cholesterol, particularly if they also have other concurrent risk factors such as hypertension, obesity, diabetes or are smokers.

H. Cigarette Smoking. Patients must be instructed to quit.

I. Exercise. Encourage aerobic exercise as tolerated.

J. Drug Therapy.

1. Dietary restriction, exercise, and weight loss should be continued for at least 3-6 months prior to consideration of drug therapy in most instances. See Tables 2 and 3.

2. Patients should be instructed that drugs are not a substitute for diet and that dietary restriction must continue.

3. Patients must be informed of the side effects of the drugs they are given. Side effects may be more tolerable when patients are told to expect them. Advise patients in strategies to minimize side effects.

4. Physician consulation prior to instruction institution of drug therapy for cholesterol reduction.

5. Be sure to consider possible interactions between lipid lowering agents and other medications the patient might be taking. Many of the lipid lowering agents affect the absorption of other drugs.

K. Lab. Fasting cholesterol, triglycerides, HDL and calculated LDL and VLDL every 3-6 months.

L. Follow-Up: Every six months initially. Every six to twelve months when controlled and stable.

TABLE 1

NURSE PRACTITIONER DIETARY PROTOCOL

| Dietary Parameter | Type I or V | Type IV | Type IIa | Type IIb or III |
|---|---|---|---|---|
| Attain and maintain ideal body weight | + | + | + | + |
| Total fat % of energy | 10-20 | 20-30 | 25-30 | 20-30 |
| Dietary cholesterol mg/day | ND | 300 | 150-250 | 150-250 |
| Polyunsaturated/saturated fat ration | ND | 1-1.5 | 1.5-2.0 | 1.5-2.0 |
| Alcohol ounces/day | 0 | 1 | ND | 1 |
| Carbohydrates % energy | 60-70* | 50-60* | ND | 50-60* |
| Fiber intake | + | + | + | + |

* Limit monosaccharides and disaccharides (lactose, sucrose, fructose) to 25% or less of total carbohydrate intake.

ND: This parameter not specifically defined for this HLP pattern.

TABLE 2

NURSE PRACTITIONER TREATMENT ALGORITHM FOR ELEVATED CHOLESTEROL

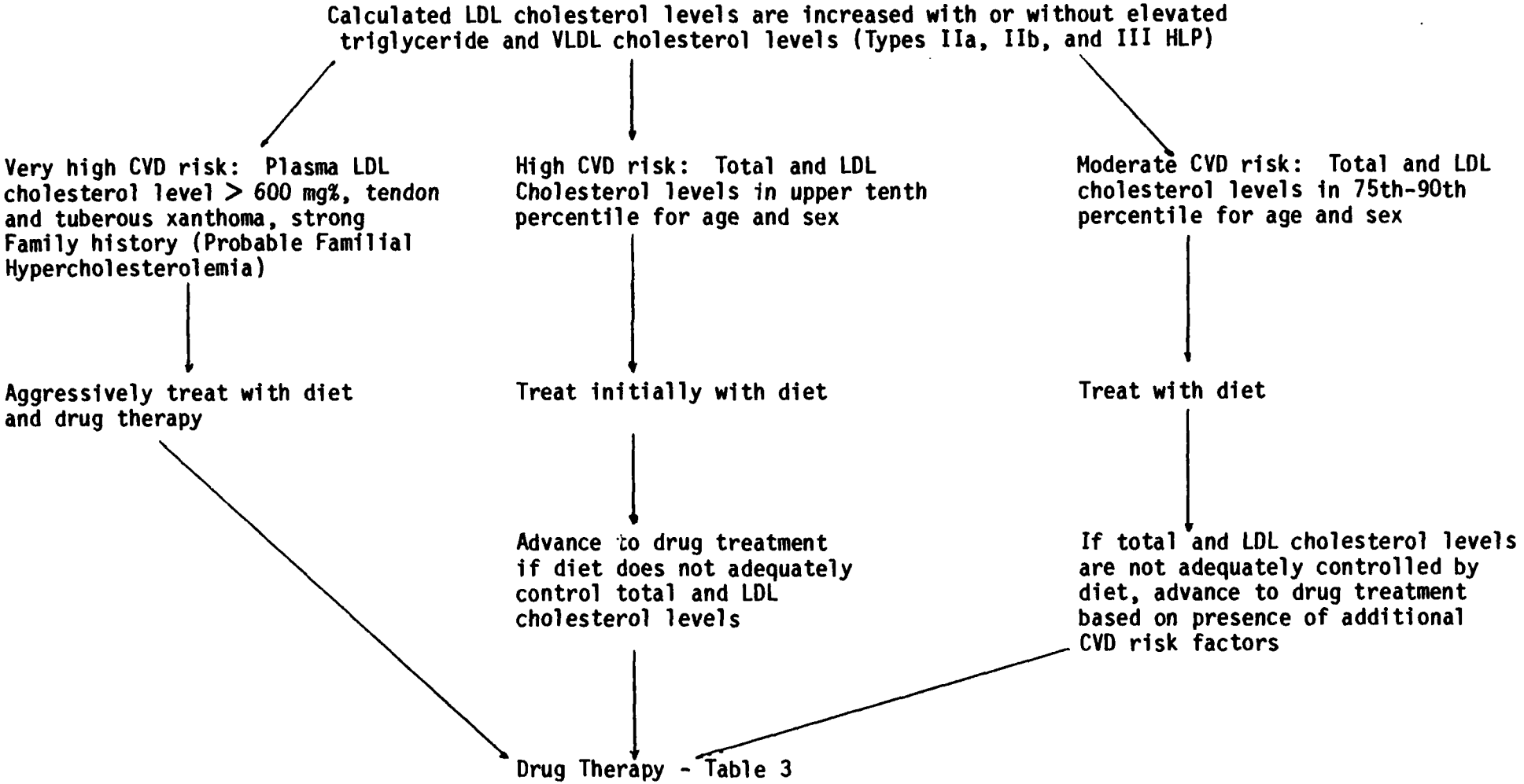


TABLE 3

NURSE PRACTITIONER ALGORITHM FOR
DRUG TREATMENT OF ELEVATED CHOLESTEROL

If diet therapy fails to normalize
LDL cholesterol level after 3-6 mo.

↓

Begin Cholestyramine resin as initial drug of choice.
Contraindications: complete biliary obst.

Start with 4 gms BID
Build to full dose of 24 gms a day by
increasing dose every 1-2 weeks.
Warn pt. about constipation.
Prescribe stook softener or stimulant
laxative prn.
Take other drugs 1 hr before or 3-4 hours after doses.

↓

If LDL levels normalize,
cont. regmen and F/U
every 3-6 months

If contraindicated, or if cholestyramine
fails to normalize LDL, or is poorly
tolerated, guide further treatment by
triglyceride (VLDL) levels.

↓

If fasting triglyceride level
start or add niacin.
Contraindications: Diabetes Mellitus
Peptic ulcer
disease
Symptomatic gout
Start with 100mg TID with meals.
warn pt. about flushing.
Use ASA 325mg 1-2 hr before each dose
if flushing severe.
Avoid hot drinks with drug.
Evaluate LFTs, FBS, and uric acid levels
after reaching 3 gm/day dosage reached
and every 6 months thereafter.
Increase dose slowly, by no more than
100mg TID each week.

If fasting triglyceride level >250 mg %
or if niacin contraindicated, start or
add gemfibrozil 1.2 gms/day (600 mg BID)
Contraindications: Severe renal disease
Hepatic disease
Gall bladder disease

↓

May increase effects of oral anticagulants
Advise pt to seek follow-up immediately
if they note symptoms of fever and chills
or sore throat or severe stomach pain
with nausea and vomiting.
Evaluate CBC and LFTs every 6 months.

↓

If LDL levels normalize, continue
regimen and F/U every 3-6 months.

If LDL levels fail to normalize, or if
contraindications to above meds exist,
or if pt. unable to tolerate above meds,
refer to M.D. for further treatment and
follow-up.

## APPENDIX B

## INTRODUCTION TO THE FAT CONTROLLED DIET

Before discussing the fat controlled diet, it is important that you understand some basic terms:

PLAQUE is a callous-like deposit along the walls of the arteries. Cholesterol is one of the main substances found in plaque.

ATHEROSCLEROSIS is a build-up of plaque in the arteries which results in a narrowing and loss of elasticity of the arteries.

CHOLESTEROL is a fat related substance which is found in your body. Your body actually makes cholesterol and it is necessary in order to produce certain hormones. Dietary cholesterol is found only in foods of animal origin.

SATURATED FATS are most easily described as fats which are solid at room temperature. Most saturated fats come from animal sources. Fats such as butter, lard, the fat found in meat, cream, and whole milk are saturated fats. Some plant sources of saturated fat include coconut oil (found in non-dairy cream substitutes and toppings), palm oil (found in some margarines), and cocoa butter (found in chocolate). Saturated fats help to raise the level of cholesterol in your blood.

POLYUNSATURATED FATS are most easily described as fats which are liquid at room temperature. Polyunsaturated fats come only from plant sources. Fats such as corn oil are unsaturated. Polyunsaturated fats help to lower the amount of cholesterol in your blood.

Frying foods: It is important to know that a polyunsaturated fat can be changed into a saturated fat. This is called hardening or hydrogenation. The oil is made hard or semi-solid. Vegetable shortenings were at one time vegetable oils but were hardened into a solid, saturated fat. Hardened fats are saturated and as such will cause elevation of choleserol levels in the blood. Thus, cooking with vegetable shortening is not recommended as it is the same as cooking with saturated fat. Cooking and frying should be done with vegetable oil.

In general, the American diet is to high in total fat, especially saturated fat, cholesterol, and sugar. The following are some important dietary principles:

1. Decrease your total fat intake.

2. Decrease your cholesterol intake.

3. Limit your intake of saturated fats and, when possible, substitute with polyunsaturated fats.

4. Decrease your sugar and alcohol consumption.

5. Increase your fiber intake.

INTRODUCTION TO THE FAT CONTROLLED DIET

To help achieve these dietary principles, the following dietary recommendations are made:

Meat Group: Trim all visible fat before cooking; use choice or good grade, avoid prime grade; preferably bake, broil or stew; if possible, cook meat on a rack or BBQ grill so the meat does not cook in its own fat; if frying meat, fry in one of the suggested oils.

| ALLOWED | AVOID |
|---|---|
| **Use more frequently:** | |
| Chicken (remove skin) | Poultry skin |
| Turkey (remove skin) | Duck |
| Veal Goose | |
| Fresh and Salt Water Fish | *Crayfish |
| *Salmon and Tuna - water packed | * Fish Roe |
| *Clams | Heavily marbled and fatty meats |
| *Crab | *Cold Cuts |
| *Lobster | *Canned Meats |
| *Oysters | *Hot Dogs |
| *Scallops | *Sausage |
| *Anchovies | *Bacon |
| Egg Whites | *Salt Pork |
| Cholesterol free-egg substitutes | *Corned Beef |
| | *Pigs' Feet |
| | Regular Hamburger |
| | *Meat canned or frozen in sauce of gravy |
| | *Frozen or packaged dinners |
| | Organ meats |
| | Commercially fried meat, fish or poultry |

Use Less Frequently:

Beef
*Ham
*Canadian Bacon
Lamb
*Shrimp - limit to 3-4 ounces per week
Liver - limit to 3-4 ounces per week

*Foods high in sodium
#Foods high in fiber

| ALLOWED | AVOID |
|---|---|
| **Meat Substitutes:** | |
| #Dried beans, Peas and Lentils | Soybean meat substitutes with saturated fat added |
| *Soybean meat substitutes which have no saturated fat added | Dried beans and peas seasoned with bacon fat, *salt pork or *ham hocks |
| *Nuts, except those excluded | Egg yolks - limit to 3 per week, including eggs used in cooking, sauces and batters, and other foods containing egg yolks. |
| | #*Cashews |
| | #*Macadamian nuts |
| **Dairy Products:** | |
| Skim Milk | Whole Milk |
| *Buttermilk made from skim milk | Chocolate Milk |
| Evaporated Skim Milk | Evaporated Milk |
| Yogurt made from skim milk | Cream |
| Non-fat dry milk powder | Ice Cream |
| Fruit ices | Cream Cheese |
| Sherbert (1-2% fat) | Sour Cream |
| Ice Milk | Half & Half |
| *Cheese made from skim milk | Whipped Cream |
| Low-fat cottage cheese | Yogurt made from whole milk |
| -Sapsago Cheese | *Cheese made from whole milk or cream |
| -Baker's | -American |
| -Farmer or Hoop | -Cheddar |
| -Specially manufactured cheese with polyunsaturated oils substituted | -Bleu or Roquefort |
| | -Camembert |
| | -Edam |
| | -Gouda |
| | -Ricotta |
| | -Swiss |
| | -Pasteurized Processed Cheese |
| | Non-Daily Cream Substitutes |
| | -Imitation Sour Cream |
| | -Imitation Toppings |
| | -Imitation Coffee Creamer |
| | Mellorine |
| | Egg Nog |
| | Malted Milk |
| | Milkshakes |
| **Fruit Group:** | |
| No Limitation | |
| Dried or Fresh (with peeling) Fruit | |

*Foods high in sodium
#Foods high in fiber

| ALLOWED | AVOID |
|---|---|
| **Vegetable Group:** | |
| Fresh, frozen or *canned vegetables | Commercially fried vegetables such as *potato chips, onion rings, french fries, okra, eggplant |
| #Raw Vegetables especially carrots, celery | Buttered or creamed vegetables prepared with excluded fats |
| #Potato skin | |
| **Breads and Cereals:** | |
| Breads | Commercial biscuits, muffins, cornbread, cakes, cake mixes, cookies, fried pies, cupcakes, pancakes, waffles, all-purpose mixes, doughnuts, butter rolls, sweet rolls and pastries |
| #-Whole wheat | *Crackers; except those allowed |
| -Rye | *Chips |
| -White | Egg Bread |
| -Raisin | Cheese Bread |
| -French | Commercial mixes containing dried eggs and whole milk |
| -Italian | Egg noodles |
| -Oatmeal | Cereals containing coconut or coconut oil |
| -Pumpernickle | |
| -French rolls | |
| #-English muffins (whole wheat) | |
| -Sour dough bread | |
| Tortillas made with polyunsaturated oil | |
| Biscuits, waffles, and pancakes made with allowed oils, skim milk and within egg allowance | |
| Bread sticks | |
| Crackers | |
| *Saltines | |
| *Soda Crackers | |
| #*Whole Wheat | |
| Melba Toast | |
| Graham Crackers | |
| *Rye Wafers | |
| *Pretzels | |
| Matzo | |
| Spaghetti, lasagna, macaroni | |
| Hot cereal | |
| #Pure Bran | |
| Cold Cereal; except those not allowed | |
| Grits | |
| Rice | |
| #Brown Rice | |
| Barley | |
| #Wheat Germ | |

*Foods high in sodium
#Foods high in fiber

| ALLOWED | AVOID |
|---|---|
| #Whole Wheat Products, i.e., W.W. spaghetti, flour, cereals | |
| Fat Group: | |
| Tub margarine listing liquid safflower or liquid corn oil as the first ingredient | Butter |
| Polyunsaturated oils | Lard |
| -Safflower Oil | Stick margarine |
| -Corn Oil | Palm oil |
| -Soybean Oil | Coconut oil |
| -Sesame Seed Oil | Products with coconut oil |
| -Sunflower Oil | *Salt Pork |
| -Cottonseed Oil | Bacon and meat drippings |
| -Walnut Oil | Gravies and sauces unless made with allowed oils |
| Mayonnaise | Solid shortening |
| *Salad dressings made with poly-unsaturated oils or not containing sour cream or cheese | *Salad dressing made with sour cream or cheese |
| -French | -Bleu cheese |
| -Italian | -Roquefort |
| and vinegar made with allowed oil | -Green Goddess |
| -Mayonnaise-type dressing | Small amounts of peanut or olive oil may be used occassionally for flavoring, however, should not be substituted for polyunsaturated oils |

The following miscellaneous foods should also be AVOIDED:

*Commercial soups made with whole milk
#*Bean and split pea soup made with ham or bacon
Chocolate
Chocolate candies and sauce
Cheesecake
#Coconut
Coconut candies
Sauces made with saturated fat, whole milk, or eggs
Pudding made with whole milk

*Foods high in sodium
#Foods high in fiber

LISTING OF PAMPHLETS
PROVIDED BY THE DIETITIAN

An Eating Plan for Health Americans (1985) American Heart Association

Cholesterol and Your Heart (1984) American Heart Association

Nutrition Labeling: Food Selection Hints for Fat-Controlled Meals (1978) American Heart Association

Recipes for Fat-Controlled Low Cholesterol Meals (1975) American Heart Association

Smoking and Heart Disease (1981) American Heart Association

Eating for a Healthy Heart (1984 revised) American Heart Association

APPENDIX 3

COMPUTATIONS

GROUP, SEX, SEX*GROUP, OVERWEIGHT, VISITS, AGE

CLASS LEVEL INFORMATION

| CLASS | LEVELS | VALUES |
|---|---|---|
| SEX | 2 | F M |
| GROUP | 2 | 1 2 |
| OVERWGTA | 2 | N Y |

NUMBER OF OBSERVATIONS IN DATA SET = 59

| GROUP | OBS | DEPENDENT VARIABLES |
|---|---|---|
| 1 | 57 | CHOLCHG |
| 2 | 56 | WTCHG |

Note: Variables in each group are consistent with respect to the presence or absence of missing values.

F TEST CHOLESTEROL

DEPENDENT VARIABLE: CHOLCHG

| SOURCE | DF | SUM OF SQUARES | MEAN SQUARE | F VALUE | PR > F | R-SQUARE | C.V. |
|---|---|---|---|---|---|---|---|
| MODEL | 6 | 10880.99947691 | 1813.49991282 | 2.22 | 0.0563 | 0.210354 | 783.2514 |
| ERROR | 50 | 40845.98297923 | 816.91965958 | | ROOT MSE | | CHOLCHG MEAN |
| CORRECTED TOTAL | 56 | 51726.98245614 | | | 28.58180644 | | -3.64912281 |

| SOURCE | DF | SUM OF SQUARES | F VALUE | PR > F |
|---|---|---|---|---|
| GROUP | 1 | 4921.40573551 | 6.02 | 0.0176 |
| SEX | 1 | 4130.43074139 | 5.06 | 0.0290 |
| SEX*GROUP | 1 | 599.11545669 | 0.073 | 0.3959 |
| OVERWGTA | 1 | 33.59428910 | 0.04 | 0.8401 |
| VISITS | 1 | 1448.36187695 | 1.77 | 0.1891 |
| AGE | 1 | 352.69853814 | 0.43 | 0.5141 |

CHOLESTEROL CHANGE

| GROUP | CHOLCHG LSMEAN |
|---|---|
| 1 | 9.2351399 |
| 2 | -16.3569708 |

| GROUP | CHOLCHG LSMEAN |
|---|---|
| F | 6.7142310 |
| M | -13.8360618 |

| SEX | GROUP | CHOLCHG LSMEAN |
|---|---|---|
| F | 1 | 22.9483620 |
| F | 2 | -9.5199001 |
| M | 1 | -4.4780821 |
| M | 2 | -23.1940415 |

F TEST WEIGHT CHANGE

| SOURCE | DF | SUM OF SQUARES | MEAN SQUARE | F VALUE | PR > F | R-SQUARE | C.V. |
|---|---|---|---|---|---|---|---|
| MODEL | 6 | 1225.71802063 | 204.28633677 | 2.67 | 0.0253 | 0.246623 | 349.6602 |
| ERROR | 49 | 3744.28197937 | 76.41391795 | | ROOT MSE | | WTCHG MEAN |
| CORRECTED TOTAL | 55 | 4970.00000000 | | | 8.74150547 | | -2.50000000 |

| SOURCE | DF | SUM OF SQUARES | F VALUE | PR >F |
|---|---|---|---|---|
| GROUP | 1 | 1041.89362049 | 13.63 | 0.0006 |
| SEX | 1 | 17.98483905 | 0.24 | 0.6297 |
| SEX*GROUP | 1 | 8.17202024 | 0.11 | 0.7450 |
| OVERWGTA | 1 | 60.72117541 | 0.79 | 0.3771 |
| VISITS | 1 | 594.51587772 | 7.78 | 0.0075 |
| AGE | 1 | 31.21316115 | 0.41 | 0.5257 |

## WEIGHT CHANGE

| GROUP | WTCHG LSMEAN |
|---|---|
| 1 | 3.63892071 |
| 2 | -8.32587079 |

| SEX | WTCHG LSMEAN |
|---|---|
| F | -1.63157079 |
| M | -3.05537929 |

| SEX | GROUP | CHOLCHG LSMEAN |
|---|---|---|
| F | 1 | 4.75323102 |
| F | 2 | -8.01637261 |
| M | 1 | 2.52461039 |
| M | 2 | -8.63536898 |

## APPENDIX 4

## COMPUTATIONS OF SIGNIFICANT VARIABLES

## GROUP, SEX, SEX*GROUP

### CLASS LEVEL INFORMATION

| CLASS | LEVELS | VALUES |
|---|---|---|
| SEX | 2 | F M |
| GROUP | 2 | 1 2 |

NUMBER OF OBSERVATIONS IN DATA SET = 59

| GROUP | OBS | DEPENDENT VARIABLES |
|---|---|---|
| 1 | 59 | CHOLCHG |
| 2 | 57 | WTCHG |

Note: Variables in each group are consistent with respect to the presence or absence of missing values.

F TEST CHOLESTEROL

DEPENDENT VARIABLE: CHOLCHG

| SOURCE | DF | SUM OF SQUARES | F VALUE | PR > F |
|---|---|---|---|---|
| GROUP | 1 | 3445.07031146 | 4.32 | 0.0424 |
| SEX | 1 | 5771.98698468 | 7.24 | 0.0094 |
| SEX*GROUP | 1 | 905.61386327 | 1.14 | 0.2913 |

CHOLESTEROL CHANGE

| GROUP | CHOLCHG LSMEAN |
|---|---|
| 1 | 3.5904762 |
| 2 | -11.7669683 |

| GROUP | CHOLCHG LSMEAN |
|---|---|
| F | 5.88509804 |
| M | -14.0274725 |

| SEX | GROUP | CHOLCHG LSMEAN |
|---|---|---|
| F | 1 | 17.4666667 |
| F | 2 | -5.7647059 |
| M | 1 | -10.2857143 |
| M | 2 | -17.7692308 |

GENERAL LINEAR MODELS PROCEDURE

F TEST WEIGHT CHANGE

| SOURCE | DF | SUM OF SQUARES | MEAN SQUARE | F VALUE | PR > F | R-SQUARE | C.V. |
|---|---|---|---|---|---|---|---|
| MODEL | 3 | 677.11842502 | 225.70614167 | 2.69 | 0.0547 | 0.132159 | 401.6034 |
| ERROR | 53 | 4446.39034691 | 83.89415749 | | ROOT MSE | | WTCHG MEAN |
| CORRECTED TOTAL | 56 | 5123.50877193 | | | 9.15937539 | | -2.28070175 |

| SOURCE | DF | SUM OF SQUARES | F VALUE | PR > F |
|---|---|---|---|---|
| GROUP | 1 | 543.47962758 | 6.48 | 0.0139 |
| SEX | 1 | 77.21201079 | 0.92 | 0.3417 |
| SEX*GROUP | 1 | 26.84304801 | 0.32 | 0.5740 |

LEAST SQUARES MEANS: WEIGHT CHANGE

| GROUP | WTCHG LSMEAN |
|---|---|
| 1 | 0.86666667 |
| 2 | -5.36425339 |

| SEX | WTCHG LSMEAN |
|---|---|
| F | -1.07450980 |
| M | -3.42307692 |

| SEX | GROUP | WTCHG LSMEAN |
|---|---|---|
| F | 1 | 2.73333333 |
| F | 2 | -4.88235294 |
| M | 1 | -5.84615385 |
| M | 2 | -17.7692308 |

## CALCULATED MEANS

### SEX

| | FREQUENCY | CHOLESTEROL CHG | WTCHG |
|---|---|---|---|
| MALE | 32 | 5.125 | -1.313 |
| FEMALE | 27 | -13.889 | -3.520 |

### GROUP

| | | | |
|---|---|---|---|
| GROUP 1 | 29 | 4.069 | 1.074 |
| GROUP 2 | 30 | -10.967 | -5.300 |

### GROUP*SEX

| | | FREQUENCY | CHOLESTEROL CHG | WTCHG |
|---|---|---|---|---|
| GROUP 1 | MALE | 14 | -10.286 | -1.000 |
| | FEMALE | 15 | 17.467 | 2.733 |
| GROUP 2 | MALE | 13 | -17.769 | -5.846 |
| | FEMALE | 17 | -5.765 | -4.822 |

Figure 1.

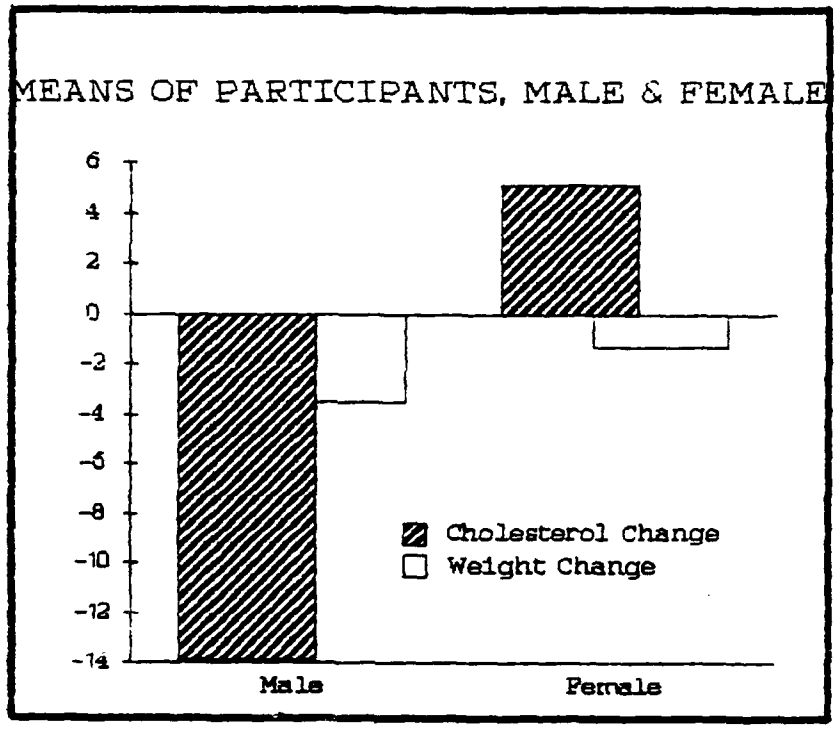



Figure 2.

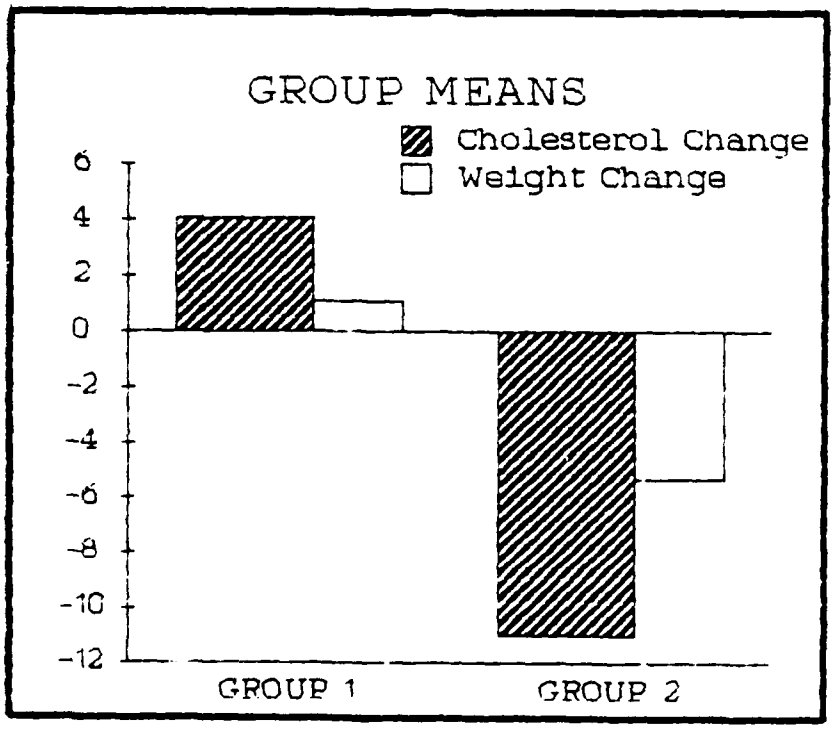


Figure 3.

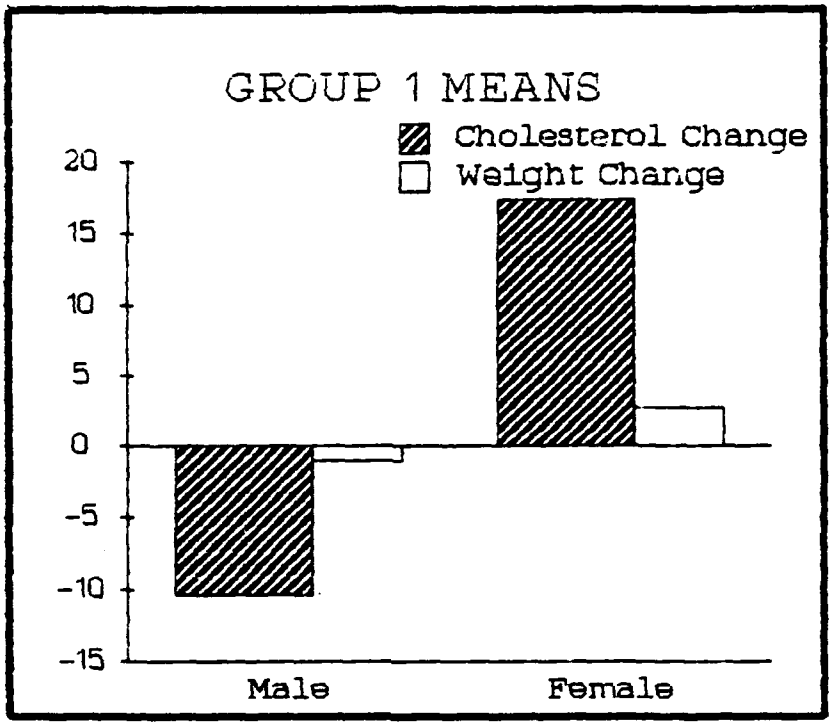
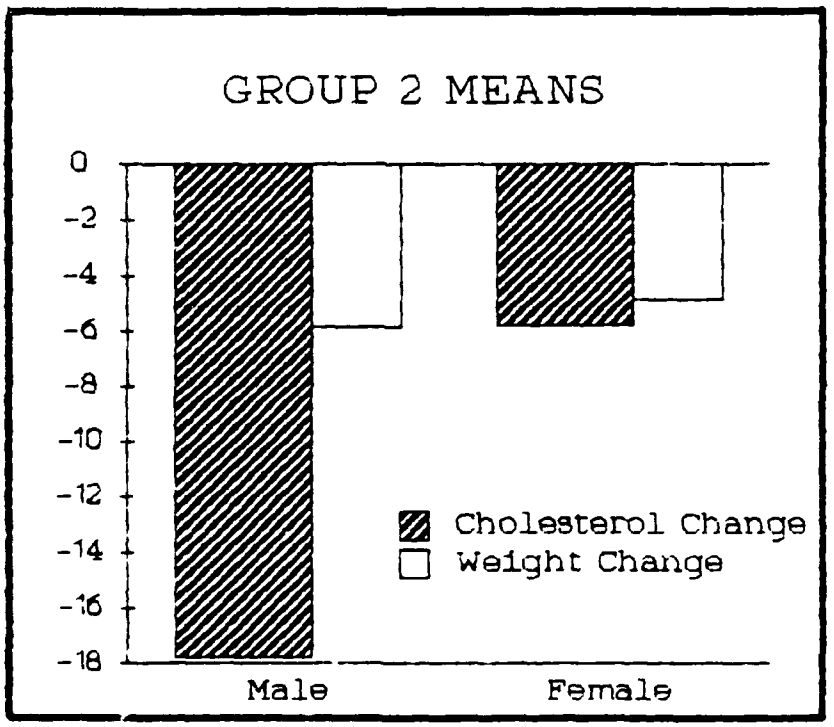



Figure 4.



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